The visibility of equity and socioeconomic determinants in Australian clinical practice guidelines

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DECLARATION

I certify that this dissertation does not incorporate without acknowledgment any material previously submitted for a degree or diploma in any university; and that to the best of my knowledge and belief it does not contain any material previously published or written by another person except where due reference is made in the text.

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Date

SUMMARY

Clinical practice guidelines (CPGs) are systematic statements that communicate evidence-based recommendations about health care for specific health conditions. In public health terms, CPGs may systematically create inequity through recommendations for treatment or healthcare delivery. For example, not considering disadvantaged groups in CPG recommendations may result in poorer access to a health intervention or in poorer health outcomes for those groups. CPGs may also systematically lessen inequity by including recommendations which redress the impact of disadvantage in healthcare delivery, for example, by including recommendations that incorporate evidence about overcoming differential health access of disadvantaged groups.

The focus of this research is twofold: firstly to examine, using an equity lens developed by the candidate, whether consideration of equity, socioeconomic determinants and disadvantaged groups, including Aboriginal and Torres Strait (ATSI) populations, is visible in Australian clinical practice guidelines on the National Health and Medical Research Council's (NHMRC) Australian CPG Portal, in the policy-relevant National Health Priority Areas; and secondly to identify, through quantitative methods, the characteristics of guidelines that demonstrate consideration of equity.

To develop the equity lens, a systematic literature search and critical appraisal of the literature was conducted. In response to the identified knowledge gap, the Australian Guideline Equity Lens (AGEL) was developed using a policy Delphi process, followed by pilot testing. Psychometric qualities of the lens were assessed and an online version developed.

Seventy-four CPGs addressing Australia's National Health Priority areas, as accessed via the NHMRC's CPG Portal and published between 2010 and 2014, were reviewed. Data were collected on whether and how equity, socioeconomic determinants and disadvantaged populations were considered. The association between methodological quality of the CPG and inclusion of equity considerations was examined quantitatively through multivariate analysis.

Overall, equity, socioeconomic determinants and the needs of specific populations were invisible in most Australian CPGs studied. Only 23 (31%) CPGs referred to socioeconomic considerations. Explicit consideration of the needs of ATSI populations was addressed in less than half (n=33, 45%) of the national guidelines. There was no significant association between consideration of equity and socioeconomic determinants in CPGs and methodological quality of guidelines. However, there was a significant association between consumer involvement in CPG development and consideration of socioeconomic determinants. Analysis also demonstrated an association between consumer involvement in CPG development and consideration of the needs of ATSI populations. Despite the public health significance of cancer, estimated to affect one million Australians over 30 years, of the 26 cancer CPGs, only six (23%) mentioned equity or socioeconomic determinants while only nine (35%) specifically mentioned ATSI populations or their needs.

This research has identified quantitatively that equity and socioeconomic determinants are not visible in many Australian CPGs. The findings have relevance for public health policy change. For example, parameters from the AGEL could be incorporated into the revision of existing NHMRC standards for CPGs to strengthen considerations of equity, socioeconomic determinants and disadvantaged populations. This dissertation includes a plan for dissemination of research evidence to influence public health policy.

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In this research, I have used and cited the iCAHE instrument for rapid assessment of methodological quality of guidelines and would like to acknowledge and thank the developers of this tool for making it publicly available for use through their publication of it.

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DEDICATION

This dissertation is dedicated to my dear parents, the late Drs Vatsala and Jiban Gupta, who supported me, encouraged me, loved me and put me first, right up to the last minute of their lives. Their bravery, intelligence and resilience and the academic paths they took have led me to this place and it is only because of them, their guidance, love and their belief in me that I commenced doctoral study. I took great inspiration from reading their papers published in the 1950s and 1960s and finding their PhD theses listed online, to get to the finish line in spite of some real personal challenges over the course of this work. I would have never completed this without their spirit above me and the knowledge that I would do them proud in the same way that I am so proud of what they achieved with so very little as young new migrants in a sometimes harsh and unwelcoming 1950s mid-West USA.

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ABBREVIATIONS

Abbreviation	
ACSQHC	Australian Commission on Safety and Quality in Health Care
AGREE	Appraisal of Guidelines for Research and Evaluation
ATSI	Aboriginal and Torres Straits Islander
CI	Confidence Interval
CPG	Clinical Practice Guideline(s)
INCLEN	International Clinical Epidemiology Network
NHMRC	National Health and Medical Research Council
NICE	National Institute of Clinical Excellence
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
StoRE	Synthesis and Translation of Research Evidence
WHO	World Health Organization

GUIDELINES TOOLS AND INSTRUMENTS CITED

Name of instrument	Brief explanation of tool/instrument
ADAPTE toolkit	A resource for adapting existing guidelines through a generic adaptation process
AGREE/AGREE II	Guideline quality assessment tool developed by the AGREE collaboration and funded by the Canadian Institute of Health
AGEL	Australian Guidelines Equity Lens
GRADE	Grading of Recommendations Assessment, Development and Evaluation – used to grade evidence developed by the GRADE working group
iCAHE guideline tool	International Centre for Allied Health rapid guideline assessment tool for quality
INCLEN equity	Tool for assessing equity in clinical practice guidelines
miCHE	A mini-checklist for appraisal of guideline quality
PRISMA-equity extension	Provides guidance for reporting of equity-focused systematic reviews
PROGRESS	Equity lens applied to interventions, especially in systematic reviews, PROGRESS refers to stratifiers to be considered: place of residence, race/ethnicity, occupation, gender, religion, education, socioeconomic status, social capital
SAGE model	Standards-based Active Guideline Environment: method to demonstrate integration of decision-support technology and guidelines

Chapter 1: Introduction, aims and objectives

1.1 Introduction

In this dissertation, research that explores the visibility of equity and socioeconomic determinants in Australian clinical practice guidelines is presented. Clinical practice guidelines are “statements that include recommendations intended to optimise patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative options” (National Academy of Sciences 2011, p. 3). The World Health Organization defines guidelines as “recommendations intended to assist providers, recipients of health care and other stakeholders to make informed decisions” (World Health Organization 2012, p. 1). In the context of clinical interactions between health professionals and patients, clinical practice guidelines usually deal with clinical, preventive, diagnostic or therapeutic interventions. As will be explained later in this dissertation, the consistent and widespread use of clinical practice guidelines for common conditions in populations or population sub-groups can affect the health outcomes of those populations.

The primary purpose of clinical practice guidelines is to facilitate evidence-based clinical decision-making. Davis et al. (2007, p. 3) further specify several purposes for clinical practice guidelines, which include to “improve the quality of patient care and health outcomes, summarise research findings and make clinical decisions more transparent; identify gaps in knowledge and prioritise research activities; inform public policy and support quality control”. Equity in health care is defined as “equal access to available care for equal need, equal utilization for equal need and equal quality of care for all” (Whitehead 1990, p. 5). In this research, an online instrument was developed to assess quantitatively the visibility of equity considerations in Australian clinical practice guidelines, and then applied to a sample of clinical practice guidelines on priority topics. The findings of this research, its significance and its limitations will be discussed in this dissertation, focusing on implications for public health policy and identifying areas for further research. Consistent with the objectives of the Doctor of Public Health dissertation, the actions planned to disseminate the findings to translate this research into policy will also be described and ethical considerations will be discussed. In this first chapter, the background to the research is provided, together with the aims and objectives of the two stages of the research.

1.2 Justification for considering equity, disadvantaged groups and socioeconomic determinants in clinical practice guidelines

Clinical practice guidelines have the potential to provide guidance to practitioners to assist them in considering equity in clinical practice (Aldrich et al. 2003), identify points in the clinical decision-making process where equity considerations may be a factor and avoid decisions that make inequities worse (Dans et al. 2007). For example, guidelines for screening and management of breast cancer might theoretically consider the differential impact of treatment on breast cancer outcomes, based on socioeconomic status. They may make recommendations about how the access to mammographic screening in hard-to-reach groups might be improved to maximise mammographic screening rates in these groups. The principal justification for considering equity in clinical practice guidelines is, therefore, that outcomes for individuals or populations might be affected by including or omitting consideration of equity. In addition, circumstances for disadvantaged groups could be improved by specifically providing recommendations relevant to these groups in relation to the guideline topic. Specifically, the guidelines might also consider evidence about treatment effects in disadvantaged communities, such as Aboriginal and Torres Strait Islander communities or those from culturally and linguistically diverse backgrounds, and make recommendations accordingly.

In Whitehead's seminal document for the World Health Organization, *The concepts and principles of equity and health, a fair chance for all*, equity in health care is defined as "equal access to available care for equal need, equal utilization for equal need and equal quality of care for all" (Whitehead 1990, p. 5). The corollary, inequity, refers to "differences which are unnecessary and avoidable" but, in addition, "are considered unfair and unjust " (Marmot et al. 2008, p. 1661). Justification also exists in the literature to support the consideration of equity in health care delivery as a public health issue. In a paper about the relevance of equity in health care, Ward (2009) has argued that health service provision should be just, adding that health care systems need to strive for the elimination of all systematic differences in health status between groups arising from socioeconomic differentials and other variables.

Authors (Aldrich et al. 2003; Dans et al. 2007) have advocated for the inclusion of equity considerations in guidelines for clinical consultations, for example, in clinical management of musculoskeletal conditions (Tugwell et al. 2008), in guidelines for managing patients with disabilities (Mizen et al. 2012), and in guidelines for other chronic conditions where socioeconomic factors might affect health outcomes, such as asthma (NHMRC 1999a; Aldrich et al. 2003). The basis for this is that inequities in health care are common and disadvantaged populations have poorer access to health care and poorer quality health care (Aldrich et al. 2003; Harris et al. 2003; Tugwell et al. 2006a, 2006b; Dans et al. 2007; Tugwell et al. 2008; Welch et al. 2010; Young and McGrath 2011; Lorenc et al. 2013; Brown et al. 2014; World Health Organization 2014). Clinical practice guidelines may worsen inequity in health care if the potential for inequity arising from recommendations is not fully considered (Dans et al. 2007; Nasser et al. 2009; Dans and Dans 2010; National Institute of Clinical Excellence 2012; Nasser et al. 2013).

Conversely, clinical practice guidelines might lessen inequity by explicitly communicating clinical or public health actions that would diminish systematic differences in health status or the delivery of patient care (Tugwell et al. 2006a). An example would be clinical practice guidelines that include recommendations for culturally appropriate smoking cessation treatment among Aboriginal and Torres Strait Islander patients with cardiovascular disease, noting that smoking rates among Aboriginal and Torres Strait Islander patients are significantly higher than in the overall Australian population (Australian Institute of Health and Welfare 2014). This is because evidence shows that culturally specific approaches are required to reduce smoking among Aboriginal and Torres Strait Islander men and women (Ivers 2004; Baker et al. 2006; Carson et al. 2012). Furthermore, clinical practice guidelines might lessen inequity by explicitly identifying those at risk of having less optimal clinical outcomes because of disadvantage and then specifically identifying what steps should be taken or considered to maximise outcomes. For example, it is well documented that for chronic health conditions such as diabetes, Aboriginal and Torres Strait Islanders have poorer health outcomes than the overall Australian population (Australian Institute of Health and Welfare 2014). Therefore, considerations for Aboriginal and Torres Strait Islander populations might specifically be mentioned in diabetes management guidelines for specialists and primary care physicians, for example, to identify how interventions might be modified for Aboriginal and Torres Strait Islander patients (NHMRC 1999b; Aldrich et al. 2003). Specific models of care might be needed, which may differ between specialist and primary care (Schierhout et al. 2016). Culturally specific approaches with a more secure evidence base of effectiveness in specific circumstances would also be applicable, for example.

In this research, the visibility of equity (as defined by Whitehead) in clinical practice guidelines will be explored, noting the potential impact that clinical practice guidelines might have both for improving equity of access to health care and for improving clinical (health care) and public health outcomes. The extent to which guidelines include recommendations about disadvantaged groups, including Aboriginal and Torres Strait Islander populations, will also be explored

The social determinants of health are well described in the literature as a strong factor in achieving health for all in the population and in reducing disparities (or systematic differences) in health status within populations. Braveman et al. (2011) have argued that differences in health status in populations are systemic and plausibly avoidable in many circumstances, and are often related to socioeconomic factors such as income, wealth, education, occupation, geography, or other characteristics associated with marginalisation. Further, Marmot (2005, 2007) has stated that social determinants of health (the conditions in which people are born and live) are key components of health equity, but these conditions of daily life are in turn influenced by such issues as gender equity, policy frameworks and values (Marmot 2005, 2007; Marmot et al. 2008; Friel and Marmot 2011). In Australia, the association between socioeconomic disadvantage, including poor housing conditions, on health outcomes of Aboriginal and Torres Strait Islander populations is well documented (Bailie et al. 2010; Bailie, Stevens and McDonald, 2012; Australian Institute of Health and Welfare and Australian Institute of Family Studies, 2013). From a public policy perspective, the World Health Organization Commission on Social Determinants of Health (Marmot 2009) has highlighted the need for action on equity and social determinants of health as a public health issue by improving the conditions of people’s lives. The Commission on Social Determinants recommended a number of priorities, including ensuring equity for all children, healthier environments, better and fairer employment, social protection across the life course and universal health care.

While action on the social determinants of health does not happen primarily within the clinical setting, Patel et al. (2010) stated that there are areas where clinicians may be able to contribute to action on socioeconomic factors in clinical interactions. These authors argued that it is possible in the clinical setting to implement practical reforms to address the consequent inequalities that clinicians manage on a daily basis. Examples of such practical reforms include improving communication across clinical pathways about social circumstances, or actively intervening to improve health care access for disadvantaged groups or individuals from those groups. The authors suggested that these measures might work not only by affecting the presenting condition but also by providing an opportunity to address upstream factors such as the social circumstances in which patients might be living. Patel, a cardiologist in the United Kingdom, gave an example from the acute care setting where multidisciplinary teams would consider upstream factors such as smokeless tobacco use in light of the increased prevalence of use of smokeless tobacco amongst disadvantaged and culturally diverse populations in the United Kingdom, in addition to other treatment considerations.

From a policy perspective, it is possible that clinical practice guidelines could systematise the clinical reforms that Patel et al. (2010) refer to by providing recommendations that address the impact of upstream factors. The potential for incorporating considerations about social determinants or disadvantaged groups into clinical practice guidelines to ameliorate inequity in health care access by identifying and managing upstream factors has been raised by a number of authors in the past 15 years (Aldrich et al. 2003; Dans et al. 2007; Burford et al. 2013; Nasser et al. 2013; O’Neill et al. 2014; Pottie et al. 2014). Aldrich et al. suggested that clinical practice guidelines inherently have policy frameworks and values that can influence social determinants of health at the individual and population levels (Aldrich et al. 2003; Dans et al. 2007), such as objectives to improve health status and prevent illness. Aldrich et al. argued that clinical practice guidelines also have significance for public health, not only for individuals. The public health significance of clinical practice guidelines arises because guidelines have the potential to formalise recommendations that are relevant to disadvantaged or marginalised groups such as Aboriginal and Torres Strait Islander populations in Australia, to ensure that clinicians consider these recommendations and make decisions for patients based on them. They can also document best practice in clinical care, so as to then allow for the measurement of evidence-practice gaps, particularly in relation to disadvantaged groups, such as Aboriginal and Torres Strait Islander populations with a view to improving clinical practice and consequent health outcomes in communities (Si et al. 2010; Bailie et al. 2011).

Well-designed clinical practice guidelines also have public health significance because of their potential to contribute to addressing health inequalities in circumstances where health status is a contributing factor to overall social well-being and economic stability or instability in individuals, populations and sub-populations. In public health terms, it is possible that clinical practice guidelines used for large numbers of individuals for common health conditions, such as cancer, heart disease or diabetes, as occurs with many national guidelines, could broaden health inequalities within populations or sub-populations by not addressing barriers to health care access, or by omitting recommendations that might address well-described socioeconomic differentials in risk factor prevalence or health outcomes for these conditions. Such omissions may result in further inequality in health status across the social gradient which, in turn, may contribute to further socioeconomic disparities within populations. For example, if the widely used national guidelines for management of diabetes in primary care do not consider the differential impact of socioeconomic circumstances on compliance with or access to diabetes management plans, it is possible that there will be differential impacts on health outcomes and diabetic complications related to those socioeconomic circumstances. Such differences may have the potential to introduce further disparities if the resulting poorer health status or health outcomes lead to additional disability, the inability to work and/or support a family or additional cost burdens to those with low incomes. In other words, the health complications may also affect socioeconomic factors. Further, if these consequences are inadvertently introduced systemically through poorly devised national clinical practice guidelines recommendations for highly prevalent conditions such as diabetes, there is likely to be a significant public health impact in populations or sub-populations, perpetuating disparities in social circumstances and leading to further inequity.

In this section, I have put forward justification and examples showing how clinical practice guidelines have the potential to influence the health status of populations or sub-populations and reduce or improve health disparities. Furthermore, if they are implemented in large scale and over time, guidelines have the potential to affect social circumstances or social determinants of health. This is a justification for research that explores the visibility of consideration of equity, socioeconomic determinants or disadvantaged groups in clinical practice guidelines. There is also a public health policy imperative to address any gaps identified through this research through active dissemination of research findings. This dissertation includes a description of the research, the findings and a plan for dissemination of the research outcomes.

1.3 Existing instruments to appraise the content and quality of clinical practice guidelines

There is a large body of literature exploring the methodological quality and effectiveness of guidelines and their recommendations, or the quality of the precursors of guidelines, systematic reviews (Kinnunen-Amoroso et al. 2009; Norris et al. 2011; Eccles et al. 2012; Beller et al. 2013; Grimmer et al. 2014; Machingaidze et al. 2015; Siebenhofer et al. *2*016). The purpose of existing instruments documented in this literature, and the limited focus of existing instruments in appraising equity and socioeconomic determinants in clinical practice guidelines are relevant to this research. Methodological work on guidelines quality is often endorsed by organisations such as the Guidelines International Network, an international collaboration to inform guidelines development (Ollenschläger et al. 2004). There are at least 18 countries described as having guidelines development occurring formally (Burgers et al. 2003). Audits have been published to assess whether “guidelines follow guidelines” (Shaneyfelt et al. 1999; AGREE Collaboration 2003; Shiffman et al. 2005; Eccles et al. 2012; Sabharwal et al. 2014) and these have demonstrated variable quality in the guidelines audited. Validated tools exist with which to audit the methodological quality of guidelines, including a widely used tool, the AGREE instrument (Carneiro 2004; Brouwers et al. 2010a, 2010b, 2010c, 2012; Polus et al. 2012; Grimmer et al. 2014). The purpose of guideline quality tools is “to provide a systematic framework for assessing key components of guidelines quality including the process of development and the reporting of that process” (AGREE Collaboration 2003). Guideline quality tools such as the AGREE instrument, the most recent version being the AGREE II instrument, provide valid and reliable domains with which to provide guidance to guideline developers to improve methodological quality (Brouwers et al. 2010a, 2010b, 2010c). The AGREE II instrument is commonly used in the international setting. It has 23 questions, requires two independent testers and uses a weighted domain scoring system to develop guidelines of high methodological quality, using a standard guideline development process.

The iCAHE Guideline Quality checklist is a simpler, binary scored instrument developed in Australia. It has the advantage of only requiring one user and can be used prospectively to develop, or retrospectively to audit, guideline quality. The checklist has been pilot tested and demonstrates good psychometric properties and utility as a guideline quality evaluation tool (Grimmer et al. 2014). The checklist comprises 14 features of guidelines that contribute to overall methodological quality. Application of the tool results in an aggregate score that gives an indication of the quality of the guideline, with a maximum score of 14 for high-quality guidelines and a minimum score of four. The iCAHE instrument was designed to be simpler, shorter, and more clinically-focused than the AGREE instrument (Grimmer et al. 2014). It has been used to assess the quality of 16 purposely sampled South African clinical practice guidelines, being more suitable for rapid critical appraisal of guidelines by a single user (Grimmer et al. 2016). Grimmer demonstrated that this instrument could be used with confidence to assess the quality of clinical practice guidelines, depending on needs and the time of end users. The instrument has been used to score allied health guidelines in twelve categories by the International Centre for Allied Health Evidence (International Centre for Allied Health Evidence, n.d). More recently (after data collection for this dissertation), Siebenhofer et al. (2016) published another rapid assessment mini-checklist (MiCHe) validated against the AGREE II instrument, to help practising physicians evaluate the quality and utility of guidelines rapidly.

None of the AGREE II, MiCHe or iCAHE instruments provide an explicit framework to incorporate or audit the visibility of equity in clinical practice guidelines (Brouwers et al. 2010a, 2010b, 2010c; Burls 2010). In addition, no work has been done in previous assessments of clinical practice guidelines to assess whether equity or socioeconomic determinants are considered more frequently or more fully in clinical practice guidelines of higher quality. Hence there is an opportunity, when looking at the visibility of equity or socioeconomic determinants in clinical practice guidelines, to examine the correlation between the inclusion of equity considerations and the overall quality of guidelines using existing and validated quality appraisal tools.

Other instruments related to clinical practice guidelines focus on rating the quality of evidence for guidelines of any underpinning systematic reviews (van der Wees et al. 2012). The GRADE methodology framework approach (Grades of Recommendation, Assessment, Development and Evaluation) provides guidance to rate systematically the quality of evidence and grade the strength of recommendations for guidelines (Hayward et al. 1997; Jaeschke et al. 2008; Schünemann et al. 2008; Guyatt et al. 2011a, 2011b, 2011c). This framework is recommended in current NHMRC standards for the development of clinical practice guidelines in Australia (NHMRC 2011). In discussing these methods, Guyatt noted that guideline developers must decide “what perspective they are taking” (Guyatt et al. 2011a). While an equity perspective is not explicitly mentioned in the GRADE methodology for rating evidence, there is the potential to consider equity within the GRADE methodology. Similarly, uniform methods exist for dissemination of guidelines in standardised formats such as the Standards Based Active Guideline Environment (SAGE) framework for encoding and disseminating clinical guidelines (Tu et al. 2004, 2007; Tu, Campbell and Musen 2004; National Institute of Science and Technology 2006). Again, these methods for guidelines dissemination do not take equity considerations into account. In other words, while there are a number of validated and well-used internationally recognised instruments or methodologies related to guidelines development and dissemination, none of these initiatives or instruments includes a focus on considerations of equity in clinical practice guidelines. There is, therefore, a research gap for an instrument that could be used to assess the visibility of equity in clinical practice guidelines. There is also scope to consider whether guideline quality, as measured by existing validated instruments, has any influence on consideration of equity and socioeconomic determinants in clinical practice guidelines.

1.4 Public health policy related to clinical practice guidelines in Australia

This research has policy relevance in Australia. Public health policy, as set by the NHMRC and other government bodies, has influenced the standards and approval processes for Australian clinical practice guidelines since 1999. In Australia, clinical practice guidelines development over the past two decades has been shaped by the NHMRC standards for development of Australian clinical practice guidelines through its key document, *A guide to the development, evaluation and implementation of clinical practice guidelines* (NHMRC 1999b). These standards, known colloquially as the “guidelines for guidelines” by public health policy makers, members of guidelines approvals bodies such as the NHMRC and guidelines developers, were updated in 2003. In 2011, the NHMRC developed more detailed requirements for clinical practice guidelines (NHMRC 2011). In August 2015, the Australian Commission on Safety and Quality in Health Care (ACSQHC) released a discussion paper, *Establishing national priorities for clinical practice guidelines 2015* (Marshall 2015). The stated objective of this discussion paper was to set out a model for the nomination and assessment of topics for clinical practice guideline development. As part of this process, a draft Expression of Interest Form was developed so that guidelines for prioritisation could be considered in a standard way by ACSQHC. A specific statement in the Expression of Interest form was that “comment should be made on population groups for specific attention”. These were listed as “vulnerable groups, Indigenous communities, children and young people, older people, pregnant women, people with disabilities, people from low socioeconomic groups, people from culturally and linguistically diverse groups”. Despite this focus, the 2016 NHMRC standards for clinical practice guidelines make no mention of the need to consider vulnerable groups or to take an equity perspective (NHMRC 2016).

In this context, the research reported in this dissertation is relevant to public health policy. Its other aims are to identify the extent to which the previous NHMRC standards for guidelines, or “guidelines for guidelines”, have been used, and to explore systematically the extent to which Australian clinical practice guidelines consider population groups who might warrant specific attention such as Aboriginal and Torres Strait Islanders, people from lower socioeconomic groups, people from culturally and linguistically diverse groups and people with disabilities. The research also examines the relationship between use of the NHMRC guidelines, approval by the NHMRC and the consideration of these population groups.

1.5 Existing literature about equity in systematic reviews and clinical practice guidelines

Systematic reviews were the precursors of clinical practice guidelines. In them, the results of studies such as randomised controlled trials were summarised and a synthesis provided of the entire body of evidence on the effectiveness of a specific programme, intervention or treatment in health care (Green and Higgins 2011). Judgements were made in systematic reviews about evidence and this in turn may have informed the recommendations in clinical practice guidelines. Considerable methodologic work has been done regarding the extent to which systematic reviews addressed socioeconomic evidence and equity. The Cochrane Health Equity field developed guidance for inclusion of equity in systematic reviews, the PRISMA equity extension (Cochrane Methods Equity Group 2012; Welch, Petticrew et al. 2012; Burford et al. 2013). While not directly applicable to use in clinical practice guidelines, this tool recommended that reporting in systematic reviews should include stratifiers such as race, ethnicity and age (Cochrane Methods Equity Group 2012; Burford et al. 2013; Welch et al. 2013). The inclusion of equity considerations and stratified socioeconomic evidence in guidelines requires that such information is incorporated into randomised controlled trials. The objective is to report outcomes of interventions on a stratified basis which can subsequently be incorporated into systematic reviews. Hence, it follows that clinical practice guidelines should identify areas where evidence about equity considerations is lacking or where data stratified by ethnicity and disadvantage, for example, is required before making recommendations.

Guidelines and systematic reviews are substantially different. Guidelines provide the mechanism to put evidence into practice, and development of them typically combines different levels of evidence, expert opinion, consumer input and other sources of information into practical guidance for clinicians. The research in this dissertation is relevant to this context because it aims to identify the extent to which stratifiers such as race, ethnicity and age are considered when evidence is analysed for inclusion in guidelines, and whether gaps in evidence, by stratifiers, have been identified. While there has been extensive methodologic work to develop a tool for the incorporation of equity considerations into systematic reviews (Tugwell et al. 2008; Welch, Brand et al. 2012; Welch, Petticrew et al. 2012; Lorenc et al. 2013; Nasser et al. 2013; O'Neill et al. 2014; Welch et al. 2015; Welch et al. 2016), there is only a small body of published and grey literature supporting an assessment of equity considerations in guidelines.

One of the few instruments identified was the International Clinical Epidemiology Network (INCLEN) (Dans et al. 2007) "equity lens" for users of clinical practice guidelines who might wish to know whether equity has been adequately considered. This focus on end users distinguishes it from other tools used by guidelines developers, those who develop standards for guidelines or approve guidelines (such as the NHMRC, or health professional bodies which endorse clinical practice guidelines such as the Royal Australian College of General Practitioners or Royal Australasian College of Physicians. The INCLEN audit tool is comprised of five criteria that allow users to assess how consideration of equity can affect clinical practice guidelines. The lens was proposed to identify points in the clinical decision-making process where equity considerations may be relevant, to avoid decisions that make inequities worse. The five criteria are:

1. "Do the public health recommendations in the guidelines address a priority problem for disadvantaged populations?
2. Is there a reason to anticipate different effects of the intervention in disadvantaged and privileged populations?
3. Are the effects of the intervention valued differently by disadvantaged compared with privileged populations?
4. Is specific attention given to minimising barriers to implementation in disadvantaged populations?
5. Do plans for assessing the impact of the recommendations include disadvantaged populations?" (Dans et al. 2007, p. 542)

Dans et al. applied the lens to the Philippine Heart Association Dyslipidaemia Guidelines for the management of dyslipidaemia (abnormal blood lipids) to determine, for example, whether issues of equity were adequately assessed. Dans et al. found that the guidelines could worsen existing inequities for a number of reasons. As clinical practice guidelines, they failed to assess the importance of the problem in disadvantaged populations, they did not consider the values of disadvantaged populations, they lacked specific strategies for implementation of the guideline recommendations in disadvantaged populations and lacked specific plans for monitoring the impact of the guidelines in disadvantaged populations.

The INCLEN equity lens has been used by other authors to review 36 guidelines for the management of different clinical conditions for equity considerations related to individuals with intellectual disabilities, identifying the need to incorporate equity considerations into guidelines systematically (Mizen et al. 2012). The guidelines considered were not systematically selected. The study found that of 36 guidelines, one explicitly excluded persons with intellectual disabilities. Of the others, Mizen et al. reported that the majority of guidelines did not fulfil most of the five criteria in the lens, indicating that the needs of persons with disabilities were not adequately considered in guidelines. Neither Dans et al. (2007) nor Mizen et al. considered a large national set of guidelines selected in a systematic way. In this research, a lens will be applied to a set of clinical practice guidelines, systematically chosen, to identify the extent to which equity has been incorporated into these guidelines.

Eslava-Schmalbach et al. (2011) analysed why incorporation of equity considerations into guidelines is desirable and necessary to promote equity in health care and health outcomes. The authors stated that differential effectiveness of interventions in social groups could diminish the final effectiveness of clinical practice guidelines. Specifically, they argued that if guidelines do not consider geographic, ethnic, socioeconomic, cultural diversity and access issues, they could have potentially negative effects. Furthermore, overall effectiveness of clinical practice guidelines would be improved if equity issues were included in “quality verification of guidelines”; in other words, that assessment of methodological quality should also take into account inclusion of equity issues.

Acosta et al. (2011) undertook a systematic literature review to identify methodologies and technical strategies for incorporating the concept of equity into clinical practice guidelines. They found no reports describing or evaluating an explicit methodology for doing so, but they did identify some processes which could be included in clinical practice guidelines “in order to avoid unjust differences in access to and/or the quality of the interventions that clinical practice guidelines prescribe” (Acosta et al. 2011, p. 327). These processes included target population involvement during all phases of design, implementation and evaluation of clinical practice guidelines; “cultural translation” of clinical practice guidelines; consideration of psychosocial factors that could affect implementation of clinical practice guidelines and consideration of system inequities that have effects on clinical practice guidelines. Following this preliminary work, the application of an equity lens or audit tool to a set of national guidelines is yet to be evaluated and reported in the published literature. The research in this dissertation applies an “equity lens” to a comprehensive set of national guidelines in Australia.

Based on a detailed review of four Australian clinical practice guidelines in 1999, the NHMRC published a document proposing a framework for incorporating socioeconomic evidence in clinical practice guidelines (NHMRC 1999a). This framework comprised a series of steps to search the literature for any evidence that socioeconomic position affected a clinical intervention, identify interventions that addressed barriers or opportunities to achieve equal health gains, and then synthesise evidence from these steps to develop clinical recommendations. As examples, the framework was applied to the development of recommendations for asthma risk identification, type 2 diabetes, diagnosis and management of breast cancer in primary care, and cardiovascular disease. The extent to which the framework recommended by the NHMRC has been adopted in subsequent clinical practice guidelines development in Australia has not been reported until the present project was designed and completed.

Further, in 2011 the NHMRC released revised standards for clinical practice guidelines (NHMRC 2011) that included a range of criteria which had to be met for NHMRC approval of the guideline. These standards suggested, but did not mandate, inclusion of broad criteria relating to inclusion of socioeconomic factors in guidelines.

The extent to which these have been used is not known. Since the release of the NHMRC guidelines on using socioeconomic evidence, other guideline development bodies such as the National Institute of Clinical Excellence (National Institute of Clinical Excellence 2012) and the World Health Organization (World Health Organization 2014) have also developed specific guidance about considering socioeconomic evidence in clinical practice guidelines.

More recently, Shi et al. (2014) identified methodological considerations from a content analysis of 10 published papers relating to how equity considerations could be incorporated into guidelines. In this study, a systematic search was done to synthesise qualitatively the methods for incorporating equity in clinical practice guidelines. Eight methodological themes and processes on how to address equity in guideline development were identified: identifying clinical questions with possible equity issues; developing search strategies with relevant terms including eligibility criteria; appraisal of the influence of equity factors such as stratifiers; analysing different subgroup effects and consulting stakeholders to synthesise the evidence; considering barriers and facilitators of the interventions; avoidance of creating or worsening inequities when making recommendations; and minimising barriers to implementation and developing an equitable implementation strategy. The authors noted that the 1999 NHMRC guidelines for incorporating socioeconomic evidence into clinical practice guidelines (NHMRC 1999a) covered most of these themes and had the best potential to be used as a tool for guiding equity considerations in clinical practice guidelines. In this research, the extent to which the NHMRC standards were used in the development of Australian clinical practice guidelines will be explored. The literature review completed at the time of conceptualising this research project showed the paucity of systematic analysis of the contents of Australian clinical practice guidelines from an equity perspective and highlighted the need for further understanding of this in order to influence public health policy related to guidelines development and approval processes in the future.

1.6 Additional public health policy relevance of this research

In light of previous research and the policy developments discussed in this section, there was relevance from a public health policy perspective to develop an instrument in which content analysis would be used to assess and quantify the inclusion of equity and socioeconomic determinants in Australian clinical practice guidelines on the NHMRC Clinical Practice Guideline Portal. This instrument would build on existing methodological work and have usability for Australian guideline developers. The development and application of such an instrument to Australian clinical practice guidelines would have direct relevance for public health policy in Australia because it would inform future standards for Australian guidelines. The instrument would also provide an impetus for policy change if it demonstrated quantitatively that there was poor visibility of equity, socioeconomic determinants and consideration of disadvantaged populations in Australian clinical practice guidelines on the NHMRC's clinical practice guidelines portal.

The aim in this research was to develop a tool to assess quantitatively the extent to which equity is visible in Australian clinical practice guidelines. The researcher has previously conducted a feasibility study to evaluate whether such a tool could be developed and used to evaluate retrospectively the visibility of equity considerations in guidelines, through a quantitative pilot study of clinical practice guidelines in the United Kingdom (unpublished, Appendix 1). The pilot study was designed to determine how, and how often, public health guidelines developed by the United Kingdom National Institute of Health and Clinical Excellence (NICE) between 2006 and 2008 referred to equity, the degree to which strategies to minimise inequity were specifically addressed in recommendations, and whether the guidance identified gaps in research data to inform guideline recommendations. Despite equity being mentioned in 16 of the 19 guidelines, a visible policy emphasis on equity was only evident in five guidelines. Although equity was mentioned in most guidelines, this was only in the background section of the guidelines rather than being specifically addressed in guidelines' recommendations. Building on this feasibility study, in the current research an equity lens was developed and then applied it to a cohort of Australian clinical practice guidelines to determine the visibility of equity and socioeconomic considerations in clinical practice guidelines, as reported in detail in Chapters 2, 3 and 4 of this dissertation.

1.7 NHMRC Australian Clinical Practice Guidelines Portal

The NHMRC National Institute of Clinical Studies released a National Guidelines Portal in 2010 (NHMRC 2015a). This is a publicly available online clearing house, which, at 30 July 2015, had 591 nationally relevant clinical practice guidelines. The types of guidelines on the portal vary considerably and include those specifically approved by the NHMRC, evidence reviews, guidelines published in peer-reviewed journals and other types of guidelines. There is no structured format for the guidelines. Some guidelines on the portal may additionally be formally approved by the NHMRC if they are consistent with NHMRC standards (Ghersi and Anderson 2015). Guidelines are removed from the portal after five years. There were three selection criteria for guidelines included on the portal in the period covered in this study (2010–2014). These were:

- The guideline contains statements that include recommendations, strategies or information that assists health care practitioners and patients make decisions about appropriate health care for specific clinical circumstances
- The guideline was produced under the auspices of a range of (specified types of organisations)
- Corroborating documentation can be produced that a systematic literature search and review was performed during guideline development and the full text guideline is available upon request in print or electronic format (NHMRC 2014).

In 2015, selection criteria for guidelines to be included on the NHMRC Clinical Practice Guidelines Portal (NHMRC 2015a) were modified to include the need for a statement of conflict of interest. There were also more stringent criteria about guideline developers and specification that the guideline must be for the Australian context and use in Australia (NHMRC 2015a). To ensure that guidelines would be developed by recognised bodies for the Australian context, selection criteria were further modified so that, for inclusion on the portal, the clinical practice guideline needed to be produced by a medical association or specialty group, a health care organisation, a non-government agency or a government. These selection criteria did not apply to guidelines on the portal from 2010 to 2014, which is the period from which guidelines in this research were selected.

Studies of guidelines on the NHMRC Australian Clinical Guidelines Portal have focused on documenting the context of the guideline or on conflicts of interest.

Buchan et al. (2010), from the Australian National Institute of Clinical Studies that developed the portal, published a study identifying the number of Australian clinical practice guidelines from 2003 to 2007 and their key characteristics. These included who produced the guideline, whether a review date was specified and whether competing interests of the members of the guidelines group were specified. The authors found that of 3134 clinical practice guidelines identified in the study period, only 52% specified a review date and 79% did not mention conflict of interest. Similarly, Williams et al. (2011) identified organisations that were primarily responsible for five or more guidelines on the portal and reviewed 200 guidelines to ascertain whether they had a conflict of interest statement and described processes to manage this. Similar to the findings of Buchan et al. (2010), Williams et al. identified that only 15% of guidelines on the portal from these developers published conflict of interest statements and even fewer described the processes used to manage conflicts. Ghersi and Anderson (2015) also reported that Australian guidelines on the NHMRC portal did not adequately report conflict of interests and this could have implications for the interpretation of evidence, which could potentially be modified or influenced because of such conflicts. Ghersi and Anderson (2015) noted that the clinical practice guidelines on the portal were likely to be of variable methodological quality, and described many as poor, with few referring to evidence underpinning recommendations and even fewer being informed by systematic reviews. None of these studies systematically addressed overall methodological quality of the guidelines, nor whether equity or socioeconomic determinants were considered.

There has been no research published related to the NHMRC guidelines portal which explores equity in clinical practice guidelines. The extent to which the guidelines on the portal have adopted the Council’s own framework for equity considerations has not been established. There is no empirical evidence identifying whether equity, socioeconomic evidence and particularly, consideration of specific groups (for example, Aboriginal and Torres Strait Islander populations, those who are socioeconomically disadvantaged or those who are from culturally and linguistically diverse backgrounds) are considered in Australian clinical practice guidelines. This study provides information to address this knowledge gap. An analysis of the visibility of equity in guidelines may influence policy relating to the development of clinical practice guidelines in the future. The criteria used to assess the Australian guidelines may also be useful in future to audit Australian guidelines prospectively.

1.8 Context of the research in this dissertation

This research is designed to investigate whether and how equity is incorporated in a sample of Australian clinical practice guidelines on the NHMRC Clinical Practice Guidelines Portal, by developing and using a specifically designed content analysis tool, the Australian Guideline Equity Lens (AGEL). This instrument will build upon content and approaches in the guidelines previously developed by the NHMRC (NHMRC 1999a, 1999b; Aldrich et al. 2003) and the parameters used in them for inclusion of equity considerations in systematic reviews and other guideline appraisal tools, such as the INCLEN equity in guidelines tool (Dans et al. 2007), guidance from the UK National Institute of Clinical Excellence (National Institute of Clinical Excellence 2012), the World Health Organization (World Health Organization 2014) and the PRISMA-equity framework for systematic reviews (Cochrane Methods Equity Group 2012; *PLoS Medicine* editors 2012; Welch, Brand et al. 2012; Welch, Petticrew, et al. 2012; Burford et al. 2013; Welch et al. 2013; Pottie et al. 2014). These frameworks all focus on equity in guidelines or systematic reviews. The research presented in this dissertation arose from previous research in the broader field of clinical practice guidelines research and within the context of a research gap in instruments or methodologies which might quantify the visibility of equity and socioeconomic determinants in clinical practice guidelines.

1.9 Reasons for choosing to conduct research on this topic

The genesis for this research was my initial interest in the area of clinical practice guidelines (Gupta et al. 1997a, 1997b; Ward et al. 1997) and subsequent study of the concepts of equity, fairness, socioeconomic determinants, upstream factors and human rights as part of the Doctorate of Public Health coursework. In addition, this research arose from my experience with a number of clinical practice guidelines used in my public health practice, such as guidelines in communicable disease control, New South Wales Control Guidelines (NSW Health 2017) or national guidelines for management of invasive meningococcal disease (Communicable Disease Network of Australia 2014).

Work and study in the areas of equity and upstream factors identified for me that the health system had the potential to worsen inequity. I believed that policies and practices within the health system might be reviewed with an equity lens to ensure, firstly, that disadvantaged groups were considered fairly and, secondly, that policies and practices did not worsen inequity. This brought me to thinking about equity and social determinants in clinical practice guidelines specifically, because guidelines are widely used within the health system by clinicians in their daily practice. Considerable time, effort and resources are also expended in their development. The questions that then arose were, firstly, whether health equity might be influenced by clinical practice guidelines, and secondly, whether guideline developers considered equity and socioeconomic evidence in their already complex guidelines development processes. I was familiar with specific guidelines, including those listed above and guidelines for the management of breast cancer and noted that there was either very little information specific to disadvantaged populations, or if there was information in the background sections of guidelines, this did not translate into specific recommendations about management. In particular, I also perceived that while Aboriginal and Torres Strait Islander health is noted as a national priority in Australia, in health policy overall and in the health service in which I work, there was little practical guidance in the clinical practice guidelines that I have used about how the specific needs of Aboriginal and Torres Strait Islander patients might be met. I also considered that while there was national guidance in the form of NHMRC guidelines on using socioeconomic evidence in clinical practice guidelines (NHMRC 1999a), there was no mechanism available to appraise whether equity considerations had been considered in guidelines. Hence, I considered that there was a need to explore the visibility of equity and socioeconomic determinants in clinical practice guidelines in a systematic way using quantitative methods. To do this, the first step would be to develop a usable equity lens. The results of such research would in turn influence public health policy by providing evidence of the extent of equity in current guidelines on a national clinical practice guidelines portal and, in addition, the parameters developed for the equity lens could potentially be used in future national standards for clinical practice guidelines developed by the NHMRC.

1.10 Justification for focusing on clinical practice guidelines in National Health Priority Areas

In this study, clinical practice guidelines in National Health Priority Areas are examined. The National Health Priority Areas initiative was Australia's public health policy response to the World Health Organization's global strategy *Health for all by the Year 2000* and its subsequent revision (Parliament of Australia 2000). The initiative was a process to identify a list of topics or health conditions that would have the greatest priority in government policy or funding, because of the public health impact that these health conditions have on the Australian population. The National Health Priority Areas were listed by the Australian Institute of Health and Welfare (Begg et al. 2007; Australian Institute of Health and Welfare 2014, 2015) at July 2015 as cancer control, cardiovascular health, injury prevention and control, mental health, diabetes mellitus, asthma, arthritis and musculoskeletal conditions, obesity, and dementia. While the National Health Priority Areas were current at the time of this research and between 2010 to 2014, the National Strategic Framework for Chronic Conditions will supersede the National Health Priority Areas. However, this framework had not been released at the time of writing this dissertation (Australian Government Department of Health 2016).

There were specific reasons for focusing on National Health Priority Areas in this research, the most critical being the significant public health impact that National Health Priority Area conditions have on the Australian population. These nine areas cover common, prevalent and mostly chronic conditions. Cumulatively these conditions pose a significant chronic disease burden and resultant public health problems for policy makers and the Australian health system to address (Australian Institute of Health and Welfare 2014, 2015). Another reason for only including guidelines in National Health Priority Areas was that some guidelines on the NHMRC Clinical Practice Guidelines Portal relate to conditions which are extremely rare, and the impact of an equity analysis on guidelines which benefit only a small number of people may be minimal at a population level, hence such guidelines would not have public health significance. Other guidelines on the Australian Clinical Practice Guidelines Portal are not immediately suitable for a useful analysis of equity considerations. Examples include guidelines about how an individual medication is prescribed, or a protocol for how a single diagnostic test is reported, because the recommendations in these guidelines are very narrow or specific and the time frames for their implementation are often short. Given these factors, inclusion and exclusion criteria for guidelines in the study were required to maximise the relevance of this research to public health policy, with an important inclusion criterion being that guidelines considered for analysis would be in the Australian National Health Priority Areas. A focus on National Health Priority Areas is also consistent with other recent public health policy developments related to clinical practice guidelines. Incidental to this study, as mentioned previously in this chapter, the Australian Commission on Quality and Safety has specified that for future guideline development, an initial list of prioritised guidelines would be developed that also would focus on the National Health Priority Areas (Australian Commission on Safety and Quality in Health Care 2015).

1.11 Purpose of this research

The central purpose of this research is to identify and determine, using a specifically designed content analysis tool, whether Australian clinical practice guidelines included considerations about equity and socioeconomic determinants. An additional purpose of the research is to identify whether the NHMRC guidance for including socioeconomic evidence in clinical practice guidelines (NHMRC 1999a) has been used in Australian clinical practice guidelines. A third purpose is to identify through quantitative analysis the characteristics of clinical practice guidelines in which the developers had considered equity, socioeconomic determinants or disadvantaged groups in the guideline.

1.12 Aims and objectives of this research

The research is conducted in two stages, Stage 1 (Chapter 3) in which an equity lens for appraising equity and socioeconomic determinants in guidelines is developed and Stage 2 (Chapter 4) in which the equity lens is applied to Australian guidelines. In Stage 1, the aim of the research is to develop and pilot test a content analysis (appraisal) tool to determine:

- The visibility of “equity”, “inequity” and “socioeconomic determinants” in Australian clinical practice guidelines developed and published on the Australian Clinical Guidelines Portal in the period 2010–2014;

- Whether equity was given emphasis in the guidelines;
- What policies or values were stated as influencing inclusion of equity and socioeconomic considerations in these Australian guidelines;
- Whether the NHMRC framework developed for *Using socioeconomic evidence in clinical practice guidelines* was applied to these Australian guidelines; and
- The characteristics of Australian guidelines that placed an emphasis on equity and socioeconomic determinants.

Therefore, the first specific research objective of Stage 1 is to identify previous tools and frameworks which are relevant to the inclusion of equity in clinical practice guidelines and their precursors, such as systematic reviews (Chapter 2). The second research objective of Stage 1 is to develop a draft content analysis (appraisal) tool, based on the literature, previous tools, identified gaps in these tools, and the current policy context for the development of guidelines (Chapter 3). The tool is intended to meet the following specific data collection objectives:

- determine the visibility of “equity”, “inequity” and “socioeconomic determinants” in Australian clinical practice guidelines;
- determine whether equity and socioeconomic evidence were included in specific recommendations or interventions;
- identify what guidance influenced the inclusion of equity and socioeconomic considerations in guidelines where equity or socioeconomic evidence were visible;
- assess whether the NHMRC framework developed for *Using socioeconomic evidence in clinical practice guidelines* (NHMRC 1999a) has been applied to Australian clinical practice guidelines;
- determine the characteristics of Australian guidelines that place some emphasis on equity or socioeconomic determinants;
- determine the characteristics of Australian guidelines that consider equity and socioeconomic factors in the guidelines; and

- determine whether inclusion of equity or socioeconomic determinants in guidelines is associated with overall better guideline quality, as measured by the iCAHE instrument developed by Grimmer et al. (2014).

The final research objective in Stage 1 is to refine the content analysis tool with the input of an expert reference panel of Australian researchers involved in clinical practice guidelines research or equity in healthcare and then pilot test the tool.

In Stage 2 of the research (Chapter 4), the aim is to apply the content analysis tool to clinical practice guidelines relating to the National Health Priority Areas made available by the NHMRC on its National Clinical Practice Guidelines Portal (NHMRC 2015) from 2010 to 2014. The specific objective of Stage 2 of the research is to apply the content analysis tool to clinical practice guidelines that fulfilled the selection criteria of the study to examine, describe and analyse the visibility of “equity”, “inequity” and “socioeconomic determinants” in them, and to quantify the features listed in the data collection objectives above.

1.13 Summary of the inquiry conducted for this dissertation

The inquiry in this dissertation is in three parts, with a systematic literature review followed by two empirical studies. In the first study (Stage 1), a content analysis tool is developed, assessed and pilot tested, and in the second (Stage 2), the content analysis tool is applied to Australian clinical practice guidelines on the Australian Clinical Practice Guideline Portal from 2010 to 2014.

Chapter 2: Systematic literature review

A systematic search and comprehensive review of the literature was used to demonstrate that the research had not been previously conducted and to identify existing tools and guidance which assessed or addressed whether equity considerations were included in clinical practice guidelines. The methods, results and discussion of this part of the research are presented in Chapter 2.

Chapter 3: Development of the content analysis tool, Stage 1

A draft content analysis tool (AGEL Version 1) was developed using a modified Delphi consultation process with input from experts in the fields of guidelines, ethics and health equity impact assessment. The next version (AGEL Version 2) was pilot tested on a set of six New Zealand guidelines for face validity. Further feedback was incorporated following pilot testing to create the next version of the instrument. The final content analysis tool arising from this process was the AGEL Version 3. Suitable questions from this tool were tested for inter-rater reliability using a random sample of 15 guidelines from the study sample. Four public health practitioners pilot tested the tool for face validity and usability before it was applied to the guidelines.

Chapter 4: Content analysis of clinical practice guidelines in National Health Priority Areas on the Australian Clinical Practice Guideline Portal, Stage 2

In Chapter 4, the process by which the final content analysis tool, the AGEL Version 3, was applied is described. Seventy-four Australian guidelines listed on the Clinical Practice Guideline Portal (NHMRC 2015) in the National Health Priority Areas (Australian Institute of Health and Welfare 2014) and with a publication date from 2010 to 2014 were examined. The iCAHE Guideline Quality Checklist (Grimmer et al. 2014) was also applied to each guideline after the application of the AGEL Version 3 in order to explore the association between guideline methodological quality (as measured by the iCAHE instrument) and the visibility of equity and socioeconomic determinants in the CPGs. Frequencies were tabulated and associations between variables analysed.

Chapter 5: Discussion of the findings and implications

The findings of this study within the overall context of the dissertation are discussed and the implications for public health policy and practice and future research are considered. A plan for dissemination of research findings to influence public health policy is presented.

As per requirements for the Doctor of Public Health dissertation, a summary of the key findings and implications of this research for policy and practice is included at Appendix 6.

Chapter 2: Systematic search and comprehensive review of the literature

In this chapter, details of the method and results of a systematic search and comprehensive review of the literature are presented. This was conducted to demonstrate that there was no existing research on the topic and to identify tools and guidance which assessed whether equity considerations were included in clinical practice guidelines. The findings of this review will be summarised and the implications for the research in this dissertation will be discussed.

2.1 Objectives

There were a number of objectives for this systematic search and comprehensive review of the literature. The first was to identify peer reviewed publications, book chapters or grey literature that specifically addressed the topic of equity in clinical practice guidelines. The second objective was to identify all literature that provided guidance about equity or socioeconomic determinants in guidelines, or existing tools to appraise equity in clinical practice guidelines. Thirdly, the literature review was designed to identify all studies where guidelines or subsets of guidelines had been audited or reviewed with respect to equity considerations. Finally, to demonstrate the originality of the research, this review was conducted to determine that similar research had not been undertaken and published at the time of conducting the research.

2.2 Method

A systematic and comprehensive search of the literature was conducted using search engines of five key health and social science databases: Pub Med, Informit, Scopus, Web of Science, CINAHL, Google Scholar and Google (to include grey literature by using keywords in the search query bar). The search included published articles, documents on websites, grey literature and books. Search terms were used with the following combinations: [equity] or [inequality] or [socioeconomic] and [social determinants] AND [clinical guidelines] or/and [practice guidelines] in keyword, title, or MeSH headings, depending on search criteria available for each database.

These terms were chosen because they were considered most closely related to the study questions and to correspond with terminology used in previously identified literature on the topic. These were also keywords in the most relevant studies related to the study aims (Aldrich et al. 2003; Arora et al. 2007). Searches were conducted on 28–30 July 2015. Papers in English or foreign languages in translation were sought. To maximise the yield of relevant literature, a reference list search from known studies related to the topic was conducted. In addition, within the clinical practice guideline literature, other words that might have been perceived as synonymous, such as “inequality”, were also considered as a checking mechanism

A list of potentially relevant literature as identified by this broad search was prepared, then manually searched for more direct relevance to the topic, that is, the consideration of equity and socioeconomic determinants in guidelines. The assessment of relevance was done by reviewing the abstract or Executive Summary, and if these provided insufficient information on which to make this assessment, the full document was reviewed. Specifically, in this assessment the aim was to identify documents that discussed the concept of equity or inequity or socioeconomic evidence in clinical practice guidelines, or assessed specific guideline(s) for equity considerations. For journal articles or reports that focused on equity in clinical guidelines, full text copies were obtained. In deciding which articles to include, there was consideration given to whether the article would be directly relevant to the topics *of both* equity or socioeconomic determinants *and* clinical practice guidelines and would allow clarification, firstly, of whether this research had been previously conducted and secondly, that the article would be directly relevant to the development of an equity lens for clinical practice guidelines.

2.3 Results

Between zero and 880 documents were identified from each of the databases and search engines (Table 1). When these were reviewed manually (as described above) between zero and twelve documents or journal articles were found on each, highlighting that there have been very few published papers in this area.

Table 1: Systematic search of literature for equity considerations in clinical practice guidelines, July 2015

Database	**Search criteria used**	**Number of articles found on search (rows not mutually exclusive)**	**Number of relevant articles from manual search (rows not mutually exclusive)**
PubMed	MeSH, title, abstract	63	5
Informit	Title, abstract	97	1
Scopus	Title, keywords, abstract	5	5
Web of Science	Title, keywords, abstract	13	4
CINAHL	Title, abstract	0	0
Google	Keyword	880	12

Of the papers identified in Table 1, only four studies assessed whether equity or socioeconomic determinants were considered in specific clinical practice guidelines. These included the paper by Dans et al. (2007) describing an equity lens developed by the INCLEN for use in clinical guidelines that was applied to the Philippine Heart Association Lipid Guidelines (as discussed in Chapter 1). Another, by the only Australian group identified in this review, was a report that proposed a framework for considering socioeconomic position in guidelines and used four guidelines as examples (NHMRC 1999a). The authors identified gaps in each of the four guidelines and demonstrated that literature existed on these four guideline topics about differential outcomes from social stratifiers. They also noted that these stratifiers could have been more fully considered in the development of the guideline recommendations.

Fredriksson et al. (2014) discussed the Swedish National Guidelines, a regulatory arrangement of evidence-based guidelines intended to prioritise decision making, and explained how these processes represented a new aspect of evidence-based medicine and clinical practice guidelines by allowing funding prioritisation decisions to be included in the guidelines. No lens was used to assess whether equity was considered and no systematic method was described to identify how or why the selected guidelines were chosen. These four studies are summarised in Table 2 below.

Table 2: Previous studies in the peer-reviewed or grey literature assessing specific clinical practice guidelines for equity considerations

Author and year	**Setting/country**	**Target population of guideline**	**Guideline(s) reviewed**	**Process/lens used**
Dans et al. 2007	Philippines	Philippines population	1995 Philippine Lipid Guidelines	Lens developed by Dans et al.
Mizen et al. 2012	International	Persons with a disability	36 guidelines from different countries about chronic conditions	Lens by Dans et al.
Fredriksson et al. 2014	Sweden	Swedish population	Swedish national health guidelines	General assessment – no lens used
NHMRC 1999a	Australia	General population	Four Australian guidelines	A framework was applied to guidelines for asthma, diabetes, breast cancer and cardiac rehabilitation.

Table 3: Papers and reports discussing the need to incorporate considerations of equity into clinical practice guidelines

Lead author, year, title	**Main argument/outcome of paper**
National Health and Medical Research Council 1999a. Using socioeconomic evidence in clinical practice guidelines	Detailed guidance for guideline developers on how socioeconomic evidence could be incorporated into guidelines, including a framework, with application to guidelines for asthma, diabetes, breast cancer and cardiac rehabilitation.
Aldrich et al. 2003. Using socioeconomic evidence in clinical practice guidelines.	Two guidelines were found that did identify socioeconomic factors. A framework was developed to contribute to more equitable healthcare.
Wailoo et al. 2004. Efficiency, equity and NICE clinical guidelines	Methods in NICE UK guideline development programme conflated individual and societal benefit.
Dans et al. 2007. For International Clinical Epidemiology Network	Developed a lens for guideline developers
Acosta et al. 2011. The concept of equity when developing clinical guidelines	Clinical practice guidelines could be a potential route for promoting more equitable health care. A framework was proposed.
Eslava-Schmalbach et al. 2011. Incorporating equity into developing and implementing evidence-based clinical practice guidelines.	Including equity issues in clinical practice guidelines can help achieve more equitable health outcomes. Clinical practice guidelines could be tools to promote equity in care and health outcomes.
UK National Institute of Clinical Excellence 2012. Positively equal: a guide to addressing equality issues in developing clinical guidelines.	Provided a context and a checklist for incorporating equity into clinical guidelines
Shi et al. 2014. How equity is addressed in clinical practice guidelines.	Content analysis of ten papers identified eight methods for incorporating equity into guidelines
Gandjour. 2014. Welfare gains and losses caused by clinical practice guidelines.	Clinical practice guidelines which include socioeconomic evidence may result in welfare loss by overestimating cost-effectiveness. Guidelines which include cost-effectiveness would make welfare losses worse
World Health Organization 2014. *WHO handbook for guideline development.* 2nd edition.	A general handbook for guideline development including a section about equity considerations

The need to incorporate considerations of equity into clinical practice guidelines and how this might be done was discussed in 10 papers or reports (including the four summarised in Table 2). These are listed in Table 3. Of the additional six papers, the paper by Aldrich et al. (2003) was a peer-reviewed perspective which discussed the rationale, process and outcome of developing the NHMRC guidance for the inclusion of socioeconomic evidence in clinical practice guidelines (NHMRC 1999a). The authors stated that clinical practice guidelines could potentially increase health inequalities by improving the health of the advantaged more than those who were disadvantaged. They also identified a paucity of literature in this area, not finding any guidelines, models or handbooks for guideline developers that were specifically concerned with the use of evidence on socioeconomic position in developing clinical practice guidelines. The authors then proposed a four-step framework for developers of clinical practice guidelines for including the effects of position in guidelines. The steps were to identify the health decision, search for evidence of the effect of socioeconomic position in guidelines, search for interventions that reduced the effects of socioeconomic position and finally to synthesise evidence to develop recommendations. The authors concluded that routine use of the framework should result in more equitable health care. The extent to which this framework has been used in Australian clinical practice guidelines will be explored in this research (Chapters 3 and 4).

The context for the editorial in the *British Medical Journal* by Wailoo et al. (2004) was the United Kingdom’s National Institute of Clinical Excellence guidelines programme. While this editorial included “equity” in the title, it was about stating the importance of economic evaluation so that NICE guidelines did not threaten the “efficient and equitable use of scarce NHS resources” (p. 537). There was no discussion in this paper about including equity considerations or socioeconomic determinants in clinical practice guidelines.

Acosta et al. (2011) conducted a systematic literature review to identify methodologies and strategies that might result in including the concept of equity in clinical practice guidelines. No reports were found describing or evaluating an explicit methodology for incorporating considerations of equity in clinical practice guidelines. However, the authors stated that some studies suggested “related strategies and processes” (p. 327) which did not specifically refer to equity but that could be applied to the inclusion of equity in clinical guidelines. The authors suggested four strategies.

First, there should be target population involvement during all phases of designing, implementing and evaluating clinical practice guidelines. Second, cultural considerations should be taken into account when evaluating evidence. Third, developers should remember that psychosocial factors could affect implementation of guidelines, and finally, health system inequities should be considered. The authors concluded that clinical practice guidelines could be a potential route for promoting more equitable healthcare by incorporating these strategies, but did not provide an explicit method by which this could be done.

Shi et al. (2014) were also concerned with methods for inclusion of equity in clinical practice guidelines. They undertook a content analysis of checklists about when, how and to what extent equity could be incorporated into clinical practice guidelines, by doing a systematic search of published literature to identify methodological themes and processes on how to address equity issues in guideline development. Similar to the experience of other authors mentioned, only a small number of papers was identified. Shi et al. proposed a seven-step clinical practice guidelines process for developers based on the papers, especially the NHMRC documents (NHMRC 1999a, 1999b; Aldrich et al. 2003). This process included setting questions which would scope the reasons why the clinical practice guideline should consider equity and then researching the relevant evidence. The next steps proposed were appraising this evidence and formulating evidence which included equity. The final steps were considering equity in implementation and providing a flow chart in the guideline to include equity in the relevant clinical practice guideline.

The paper by Eslava-Schmalbach et al. (2011) presented a narrative and economic analysis explaining why equity should be incorporated into guidelines in the context of the government’s General Social Security and Health system in Columbia, which was promoting and implementing clinical practice guidelines with the aim of improving quality and efficiency of health care. The authors argued that it was important to incorporate equity considerations into clinical practice guidelines, claiming that differential effectiveness of interventions by social groups could diminish the overall effectiveness of clinical practice guidelines. Like other authors, they stated that failing to consider socioeconomic, cultural and diversity issues could have potential negative impacts. They noted that overall effectiveness of a clinical practice guideline could be improved if equity issues were included in quality checklists of guidelines and so guidelines could then promote equity in healthcare and health outcomes.

The document by the United Kingdom’s National Institute of Clinical Excellence, *Positively equal: a guide to addressing equality issues in developing clinical guidelines* (National Institute of Clinical Excellence 2012) provided a rationale and a checklist for considering equity issues in clinical guidelines. The document incorporated checklists for different phases of the guidelines development process, namely scoping, early guidelines development and when formulating recommendations. The focus of the checklists related to the inclusion of general questions about whether there were inequalities known in relation to the guideline topic and whether there was sufficient evidence to make recommendations. The checklist on formulating recommendations included questions to consider to “avoid discrimination” and “advance equality of opportunity” (p. 16). Examples of questions were “Do any criteria make it easier or more difficult in practice for people in a specific group to gain access to the intervention?” and “Could the recommendations advance equality for people in a specific group, either through access to the intervention or by means of the intervention?” (p. 16). Similarly, the second edition of the *WHO handbook for guideline development* (World Health Organization 2014) included six areas for guideline developers to take into account to ensure the inclusion of equity considerations in clinical practice guidelines developed for the World Health Organization. These were: does the guideline convey clear messages about equity, human rights, gender and social determinants; is there evidence that the guideline development group includes persons who understand equity issues; are conflicts of interest declared; does the guideline take into account the potential for differential uptake due to social position; do systematic reviews used in development of the guideline describe the potential effect of interventions across the social gradient; and where evidence on equity is sparse, are conditional recommendations made, outlining key gaps or a research agenda.

Finally, Gandjour (2014), an economist from Frankfurt, took a different perspective. He undertook a literature search in the German and United States clinical practice guidelines clearing houses (similar to the NHMRC portal) in 2013 to identify guidelines containing cost effectiveness analyses which considered equity or fairness. Of 2505 guidelines registered in the US clearing house, only two considered the trade-off between “equity”, “fairness” or “ethics” and cost effectiveness. Only one German guideline did this. However, Gandjour noted that a significant portion of clinical practice guidelines did consider costs and cost effectiveness without considering equity. He proposed an economic model demonstrating that guidelines which included cost effectiveness only and did not consider the trade-off between equity or fairness or ethics and cost effectiveness, would lead to greater costs to the welfare system. In other words, there was an economic argument for including equity considerations in clinical practice guidelines on the basis of welfare gains. Gandjour suggested that a public consensus on the trade-off between cost effectiveness and equity did not yet exist. He speculated that this might be required because clinical practice guidelines which include cost effectiveness only may result in economic losses.

In summary, there had been very few articles which considered equity or socioeconomic determinants within the context of clinical guidelines at the time of conducting this systematic search and comprehensive review of the literature. Seven papers or reports provided a framework or description of the types of considerations or methods that should be used in order to include guidelines (NHMRC 1999a; Aldrich et al. 2003; Wailoo et al. 2004; Dans et al. 2007; Eslava-Schmalbach et al. 2011; National Institute of Clinical Excellence 2012; Sanclemente et al. 2014; Shi et al. 2014; World Health Organization 2014). As will be discussed in later chapters, these frameworks and considerations were included in the development of the Australian Guidelines Equity Lens.

2.4 Discussion

In this systematic search and comprehensive review of the literature, few publications were identified in the peer reviewed or grey literature. Only 10 publications made specific reference to equity considerations in clinical practice guidelines in the title or abstract, some of which were not directly relevant to the practical considerations of including equity and socioeconomic factors in clinical practice guidelines development. There was a paucity of methodological work to ensure explicitly that equity considerations were assessed in guidelines development, or that recommendations about equity were included in the guidelines, or to audit guidelines for equity considerations. There have been no Australian studies published that assessed equity considerations in a series of clinical practice guidelines, although the NHMRC has published guidance in this area in the peer reviewed and grey literature, using four guidelines as examples (NHMRC 1999a; Aldrich et al. 2003), as outlined in Chapter 1.

Few studies provided frameworks by which to assess guidelines for equity and only Dans et al. (2007) developed an equity lens. This was applied to guidelines in two different contexts (Dans et al. 2007; Mizen et al. 2012) to systematise assessment of equity in clinical practice guidelines. There was some guidance from national and international bodies of the types of questions that should be included when assessing clinical practice guidelines (NHMRC 1999a; Aldrich et al. 2003; National Institute of Clinical Excellence 2012; World Health Organization 2014) that could benefit the work in this dissertation, which will explore how equity and socioeconomic determinants are expressed in guidelines. Most of the checklists or frameworks were based on the preliminary work done by the NHMRC (NHMRC 1999a). The extent to which the NHMRC's work in this area has been taken up by guideline developers will be explored in this dissertation.

This literature review has also confirmed that as of July 2015, a study to develop a tool to appraise systematically Australian clinical practice guidelines for equity considerations has not been published in the grey literature or peer reviewed journals. As will be described in Chapters 3, 4 and 5 of this dissertation, the existing instruments, standards or frameworks identified in this systematic search and comprehensive review of the literature subsequently informed the development of the content analysis tool for this research. In particular, the INCLEN equity in guidelines tool (Dans et al. 2007), NHMRC and National Institute of Clinical Excellence UK and World Health Organization standards included sections related to incorporating equity considerations into clinical practice guidelines. Some parameters from these documents or similar, were included in the AGEL developed in this research.

Chapter 3: Development of the Australian Guidelines Equity Lens (Stage 1)

3.1 Introduction

In this chapter, the development and testing of a content analysis tool for assessing equity and socioeconomic determinants in clinical guidelines, the “Australian Guideline Equity Lens” (AGEL) is described, which comprises Stage 1 of the research. The development of the AGEL was iterative, broadly occurring within three phases and producing three versions of the AGEL. In this chapter, the development of the three versions of the lens is described, followed by the evaluation of some psychometric properties (reliability, face validity and usability) of the third version, the AGEL Version 3.

More specifically, in this chapter I describe how a draft appraisal tool (AGEL Version 1) was developed using a modified Delphi consultation process, with input from experts in the fields of guidelines, ethics and health equity impact assessment. The Delphi consultation process will be described first, followed by a discussion of the use of content analysis and finally an explanation of reliability, validity and usability. Next is a description of how the second version of the tool (AGEL Version 2) was pilot tested with a set of six New Zealand guidelines for face validity and how further feedback was incorporated following pilot testing to create the third version of the instrument, the AGEL Version 3, which is included hereunder. Finally, there is an explanation of how suitable questions from this content analysis tool were tested for inter-rater reliability using a random sample of 15 guidelines from the study sample, and how the content analysis tool was pilot tested for face validity and usability with four public health practitioners including three clinicians, before being applied to the guidelines on the NHMRC Australian Clinical Practice Guidelines Portal.

3.2 Methodological issues

3.2.1 Use of content analysis and document review

In this research, the development and application of a tool to assess equity in clinical practice guidelines is underpinned by the method of content analysis, a means of analysing data as part of a document review. Neuendorf defines content analysis as "an analysis using quantitative or qualitative techniques, using a scientific method and is not limited as to the types of variables that may be measured or the context in which the messages are created" (Neuendorf 2011, p. 10). More specifically, it involves the manual coding of documents to obtain evidence or counts of words, phrases, or concepts followed by statistical analysis. According to Krippendorf, five processes are inherent to content analysis:

1. A unit of analysis must be established (e.g. guideline);
2. Units of analysis are sampled;
3. Content of data must be reduced in complexity, often by employing summary statistical measures;
4. Contextual phenomena are analysed to provide the context for findings;
5. Conclusions are usually, but not always, communicated in a narrative format (Krippendorf 2004, p. 11).

In previous guideline appraisal tools, such as the AGREE instrument, it was not explicitly stated that a content analysis approach was used in their development. However, the use of such an instrument categorises and quantifies a written communication (a guideline) prospectively and is consistent with Nuendorf's definition and Krippendorf's stated processes. In my pilot study analysis of UK National Institute of Clinical Excellence's public health guidelines I used a quantitative method of content analysis to "describe and make inferences about the characteristics of communication" (Roberts 1997). In this research, quantitative content analysis of guidelines is used to analyse guidelines on the NHMRC's Australian Clinical Practice Guidelines Portal.

The five processes stipulated by Krippendorf (2004) were included in the development and use of in the AGEL in this research. First, the unit of analysis was established as being each clinical practice guideline studied; second, the units of analysis were sampled from 558 guidelines on the NHMRC's Australian Clinical

Practice Guidelines Portal during the study period; third, the appraisal instrument allowed for reduction of the complexity of data in the guidelines and then summary statistical measures were used to quantify frequencies and key attributes; fourth, in the discussion and interpretation of the findings, the overall policy context and the context of the development of the guidelines was considered when interpreting the findings; and finally, conclusions were drawn from the results.

3.2.2 Use of the Delphi method in the development of the appraisal tool

The Delphi technique was used to develop the AGEL. The Delphi technique is a method for gathering data from respondents within their domain of expertise (Hsu and Sandford 2007a). This process can be used in various study areas including policy determination and needs assessment. The technique uses questionnaires to collect data from experts using multiple iterations. It can be used to include input on a particular topic from different disciplines (Turoff 2002). Hsu and Sandford (2007a) explain that the Delphi process includes feedback which encourages experts to reassess their views through an iteration process until consensus is achieved. They also note that choosing the appropriate persons for the Delphi expert panel is the most important step in the Delphi process because it directly influences the quality of the results. It is generally accepted that selection of the panel will be influenced by the expertise required in relation to topic (Linstone and Turoff 2002). Linstone and Turoff note that Delphi panellists should have expert knowledge of the topic in question.

Panel selection in the Delphi process is prone to selection bias and this is a significant limitation (de Villiers et al. 2005), especially because choosing appropriate persons is generally based on the judgement and discretion of the principal investigators of the research (Hsu and Sandford 2007a), which is subjective. Methods commonly used for selection include a review of authors of publications in the field and contacting experts who are known to have an interest or expertise in the issue being considered (Keeney et al. 2011). In this research, panellists for the Delphi consultation were chosen by the researcher and one supervisor, based on their knowledge of experts in the field of equity in healthcare and the experts' interest in guidelines and/or evidence-based medicine in Australia. Four people who were approached for the Delphi consultation were experts in the field of equity in healthcare. They had all published in these areas, including one primary author of a previously significant document about equity in clinical practice guidelines. The panellists who were experts in evidence-based medicine or guidelines development were also identified by the researcher’s and supervisor’s knowledge of experts in Australia in this area – they were either known leaders in the fields of health equity or equity considerations in relation to evidence-based medicine and had published in these fields, and would also be accessible.

Hsu and Sandford (2007a) noted that there is no consensus in the literature on the ideal number of experts in a Delphi study, and an optimal number of panellists might range from 10 to 50. Ludwig (1997) stated that the majority of Delphi studies used between 15 to 20 respondents. In this study, the researcher and supervisors agreed there should be an optimal number of 10 panellists. This was decided because the topic chosen, that of clinical practice guidelines and equity, was a very specific area of inquiry and as such, accessible Australian expertise was scarce, as shown by the literature review in Chapter 3.

A key methodological aspect of Delphi studies is the maintenance of panel motivation to achieve high response rates (Ludwig 1997; Hsu and Sandford 2007a). This is particularly important because the Delphi process relies on having panellists where expertise may be scarce in the topic area and also because the overall sample size of the Delphi panel is small. Ludwig (1997) noted that motivation is the key to successful implementation of a Delphi study and investigators need to play an active role in this area to help ensure a high response rate. In their paper on minimising non-response in Delphi surveys, Hsu and Sandford (2007b) pointed out that there are several well-recognised techniques that can be used to deal with non-responders and maximise response rates to multiple iterations of questionnaires during a Delphi consultation. These strategies include seeking out well-recognised experts; establishing direct contact with the panel; using different formats of questionnaires; following up non-responders and providing incentives. Many of these strategies were used in this research to maximise response rates. At the outset, it was predicted that maintaining a high response rate among busy senior academics and health professionals for a doctoral student project which required feedback on a lengthy and complex document (the draft content analysis tool) would be challenging, particularly because there would be little incentive, other than contributing to the field, to do so. Consistent with the strategies identified in the literature, and as will be described in the following section, several response-maximising strategies were employed to improve participation and subsequent response rate for further iterations of the consultation. These included seeking out well-recognised experts; the researcher directly approaching the experts with a letter and email from the supervisor to request participation; offering to obtain second and subsequent rounds of feedback by multiple modalities (in writing, by email or by telephone); active follow-up of non-responders and finally providing the (non-financial) incentive that participants would be acknowledged in any future academic work should they wished to be named. The effectiveness of these strategies will be discussed in the Results section of this chapter.

A modification of the typical Delphi process was used to seek feedback from experts in the development of the AGEL and to explore options for its content. The typical Delphi process involves the development of the question (in this case, the appraisal tool), based on literature review and previous pilot studies, followed by selection of the research panel, the release and analysis of an accompanying questionnaire, with consultation in rounds, usually about three iterations. This is then followed by research documentation, verification and generalisation, which lead to the development of the final appraisal tool (Skulmoski and Hartman 2007). In a typical Delphi process, the number of rounds may be determined by when consensus is reached, so that a decision can be made (Skulmoski and Hartman 2007). In this study, a policy Delphi approach was used in the development of the appraisal tool. This technique is useful when consensus may not be an achievable goal, or when options need to be considered. The policy Delphi is a tool for the analysis of policy issues and not necessarily a mechanism for making a decision (Linstone and Turoff 2002; Skulmoski and Hartman 2007). Gupta (2011) noted that a policy Delphi process is based on an assumption that experts are not homogenous in their point of view and that panel members may not even be experts, but instead individuals who represent various groups or interests. In a policy Delphi process, generating consensus is therefore not a prime objective, but rather may “ensure that all possible options have been put on the table for consideration” (Skulmoski and Hartman 2007). The process still uses structured information flow and regular feedback. The policy Delphi approach was used in this research because consensus was not expected to be an achievable goal. Further, using this method, options could be put on the table for consideration in making decisions based on the advice from Delphi subjects.

3.3 Validity, reliability and usability of the guideline appraisal tool

In the development of an appraisal tool such as the AGEL, consideration of the validity and reliability of the survey instrument (psychometric properties) is required. The psychometric properties of the survey instrument are relevant to the interpretation of findings and subsequently to the policy implications of the research. Newman and McNeil (1998) noted that usability, reliability and validity are all important properties of a questionnaire or audit tool. These properties were assessed in relation to the AGEL in this research.

3.3.1 Validity

Validity of a survey instrument refers to how accurately the instrument measures the variable itself (Sullivan 2011). The validity of the AGEL is relevant to ensuring that the collection of data regarding equity, socioeconomic determinants and consideration of disadvantaged populations is adequately captured with the content appraisal tool. This is to ensure that the aggregate data resulting from the use of the tool on a set of guidelines reflects the visibility of equity, socioeconomic determinants and consideration of disadvantaged populations. For this study, relevant aspects of validity are face validity and concurrent validity.

Face validity refers to an instrument appearing to measure what it claims to measure (Gaber 2010). It is the most practical measurement that can be made with a complex and detailed survey instrument that measures a number of parameters, as is the case with the AGEL. Face validity is based on subjective judgement and is difficult to quantify (Gravetter and Forzano 2009). It is commonly assessed through pilot testing. Although it is the least scientific form of defining validity (Gravetter and Forzano 2009), face validity was the most feasible aspect of validity to assess in relation to the AGEL, given that the instrument had 124 fields (as described below). Other forms of validity testing, such as assessment of convergent, divergent and concurrent validity, would necessitate comparing measurements by the tool developed for this research with results from other tools assessing equity in guidelines, in relation to the same set of clinical practice guidelines. In this research, the AGEL could potentially be compared with the International Network of Clinical Epidemiology equity lens developed in 2007 (Dans et al. 2007), for example, to assess concurrent validity. That is, whether scores from the new instrument are directly related to scores from an existing instrument (Gravetter and Forzano 2009). This method was used when the iCAHE instrument for guideline quality was developed, where content and construct validity against the existing much longer AGREE instrument for guideline quality was assessed by applying both tools to six randomly selected guidelines (Grimmer et al. 2014). However, in the case of the AGEL, there was no published information on the psychometric properties of the INCLEN equity in guidelines tool for comparison.

Concurrent validity refers to the extent to which the measurement of a construct, in this case measurement of the consideration of socioeconomic determinants by the relevant collection of a variable in the AGEL, is the same as the measurement of a construct determined by a different field, in this case a content analysis question from the INCLEN tool dimensions. In an instrument such as the AGEL it is possible to assess concurrent validity of one construct by comparing the extent of agreement between two different measurements of that construct. In this research, this was done in relation to content analysis of how frequently equity and socioeconomic determinants were measured using both a field from the INCLEN tool and an earlier field in the AGEL.

3.3.2 Reliability

Reliability refers to whether an assessment instrument gives the same results each time it is used in the same setting with the same type of subjects (Sullivan 2011). Inter-rater reliability is an important construct for an audit tool such as the AGEL. Other clinical practice guideline audit tools such as the AGREE instrument and the iCAHE instrument have been assessed for inter-rater reliability (Brouwers et al. 2010a, 2010b, 2010c; Grimmer et al. 2014), with this psychometric property being particularly relevant to the iCAHE instrument given that it is designed for one user. Inter-rater reliability of the AGREE instrument for guideline quality has been studied in detail over many years of development, finding that with the most recent version of the instrument, the number of appraisers required to reach a level of inter-rater reliability for the entire instrument ranged from two to five across various domains in the instrument (Brouwers et al. 2010a, 2010b, 2010c). Similarly, the inter-rater reliability between users of the AGEL developed in this research was calculated for key fields which quantify the visibility of equity, socioeconomic determinants and consideration of disadvantaged populations. This was done by calculating the correlation between the scores from two observers using Cohen’s kappa statistic (Cohen 1960; Bland 2000).

Inter-rater reliability is measured as a percentage agreement, calculated as the number of agreement scores divided by the total number of scores. However, this does not take into account agreement by chance (McHugh 2012). Cohen introduced the kappa statistic to account for this. Cohen’s kappa can range from +1 to –1, where 0 represents the amount of agreement that can be expected from random chance and 1 represents perfect agreement between raters. Cohen’s kappa is generally interpreted as follows: values ≤0 indicate no agreement; values 0.01–0.20 none to slight agreement; values 0.21–0.40 fair agreement; values 0.41–0.60 moderate agreement; values 0.61–0.81 substantial agreement and values 0.81–1.00 almost perfect agreement (Cohen 1960). In this research, a cut-off of >0.60 was used for Cohen’s kappa coefficient to define sufficient agreement.

3.3.3 Usability

Usability of the instrument is also relevant for future use of the lens and interpretation of the findings of this research. Usability refers to the ease with which an instrument can be administered, interpreted by the user (in this case the user of the content analysis tool) and then scored and interpreted by the user (Dignan 1995). Usability can also be assessed by pilot testing, both by the developer of the tool and other pilot testers (Wilson 2013). There is, however, minimal literature on what principles or characteristics of usability should be considered in a content analysis instrument such as the AGEL. The only relevant literature identified on usability characteristics relates to the principles for design of interactive surveys for public opinion research, rather than for appraisal instruments to be used by health professionals or educators online. These principles include suitability for the task, self-descriptiveness, conformity with user expectations, suitability for learning, controllability, error tolerance and suitability for individualisation (Kaczmirek 2005). Of these principles, the most pertinent for usability of the AGEL were suitability for the task, conformity with user expectations and suitability for individualisation. These themes were characteristics of the feedback provided by pilot testers as part of the usability testing, as described more fully below.

3.4 Aims and objectives

The aims of this study were to develop, pilot test, and evaluate the psychometric properties of the AGEL, which was developed to explore the visibility of “equity”, “inequity” and “socioeconomic determinants” in Australian clinical practice guidelines published on the Australian Clinical Guidelines Portal in the period from 2010 to 2014, and to analyse the characteristics of guidelines in which equity and socioeconomic determinants were visible.

The first specific objective of this study was to develop the AGEL based on the literature, previous tools and the current policy context for the development of guidelines. The tool was intended to meet the following specific data collection objectives:

- determine the visibility of “equity”, “inequity” and “socioeconomic determinants” in Australian clinical practice guidelines;
- determine whether equity and socioeconomic evidence were included in specific recommendations or interventions;
- identify what guidance influenced the inclusion of equity and socioeconomic considerations in guidelines where equity or socioeconomic evidence were visible;
- assess whether the NHMRC framework developed for *Using socioeconomic evidence in clinical practice guidelines* (NHMRC 1999a) has been applied to Australian clinical practice guidelines;
- determine the characteristics of Australian guidelines that place some emphasis on equity or socioeconomic determinants;
- determine the characteristics of Australian guidelines that consider equity and socioeconomic factors in the guidelines; and
- determine whether inclusion of equity or socioeconomic determinants in guidelines is associated with overall better guideline quality, as measured by the

previously developed and tested iCAHE instrument developed by Grimmer et al. (2014).

The second objective was to refine the AGEL with the input of an expert reference panel of Australian researchers involved in clinical practice guidelines research or equity in healthcare and pilot test the guidelines to finalise the content analysis tool before application to the full set of guidelines. The final objective was to assess the inter-rater reliability, usability and face validity of the AGEL.

3.5 Methods

3.5.1 Development of the Australian Guidelines Equity Lens Versions 1, 2 and 3

The first version of the content analysis tool was developed after multiple drafts. The AGEL Version 1 addressed the specific topics listed above and is attached at Appendix 2. During preparation of the content analysis tool, definitions of equity, inequity and socioeconomic determinants identified in the literature review were considered, together with the content analysis tool used in a pilot study of a sample of the United Kingdom's National Institute of Clinical Excellence clinical practice guidelines (see Appendix 1). In particular, items from the pilot study which had face validity and the recommendations of the NHMRC's document, *Using socioeconomic evidence in clinical practice guidelines* (NHMRC 1999a), were included. In addition, the AGEL Version 1 incorporated published work on guidelines appraisal for equity identified in the systematic literature review presented in Chapter 2 (NHMRC 1999a; Aldrich et al. 2003; Dans et al. 2007; National Institute of Clinical Excellence 2012; Shi et al. 2014; World Health Organization 2014).

The AGEL Version 1 was 11 pages long with five distinct sections. There were 50 fields, some open-ended and with free text, others collecting data in quantitative form. The content analysis tool included fields for collecting detailed information about the guideline (developers, publication, relevance of the guideline, what type of intervention was included in the guideline, whether there was consumer representation in the development of the guideline), lists of questions about how equity was represented in the guideline and whether gaps were identified. Fields incorporating the equity lens by Dans et al. (2007) and the NHMRC guidelines for incorporating socioeconomic evidence into clinical practice guidelines (NHMRC 1999a) were also included.

To maximise the validity of the content analysis tool, input was systematically sought from Australian experts through the policy Delphi consultation technique. Ten Australian experts were identified through networks. These experts had an interest in or were users of clinical practice guidelines, or had an interest in equity in health care, ethics of resource allocation or health care interventions. Experts who were also practising clinicians were identified. The researcher and one supervisor chose the ten experts based on their knowledge in the field of equity in healthcare in Australia, and/or an interest in guidelines and/or evidence based medicine in Australia. Four people were approached who were experts in the topic of equity in healthcare. These included two of the primary authors of a previously significant document about equity in clinical practice guidelines. Experts were then approached for recruitment for the Delphi consultation. These were experts in evidence-based medicine or guidelines development in Australia identified by the researcher and her supervisor. It was decided to identify experts who would be accessible and more likely to be willing to participate in the process, to maximise the response rate and for pragmatic reasons, because it was considered that such persons were more likely to participate actively in the Delphi consultation process. As explained in the introduction to this chapter, the rationale for choosing 10 experts was because the subject area was narrow and the expertise to choose from was limited, given the specific field of the topic area in question.

Following selection of the experts, an email was sent to each informing them about the study, followed one week later by a letter requesting their involvement. As a strategy to encourage responses, the letter included the signatures of all three principal investigators. The letter explained the proposed consultation process, which would involve commenting on three drafts of a content analysis tool in a Delphi process. An explanation of the Delphi process and a summary of the proposed study were also provided. The experts were asked to reply by email or return mail to indicate their willingness to participate and were asked to provide preferred contact details and other relevant information (areas of interest, principal areas of research, qualifications, other academic affiliations, previous involvement in guidelines research and whether they undertake clinical practice).

Of the 10 experts contacted, six agreed to participate. Of the four who did not agree to participate, two had expertise in equity in health care and two had expertise in evidence-based medicine. Each cited time constraints as the reason for choosing not to participate. The characteristics of six experts who consented to participate and how they provided comment are set out in Table 4.

Table 4: Characteristics of experts who consented to participate in consultation process

Area of expertise	**State of residence**	**Academic/clinician/other area of practice**	**Provided written comment**
Health impact assessment and equity	NSW	Academic	Yes
Guidelines and equity	NSW	Academic and clinician	Yes
Health ethics, evidence based medicine	NSW	Academic and clinician	Yes
Guidelines, as a user of guidelines	NSW	CEO, non-government organisation	No (contacted by telephone)
Evidence-based medicine	NSW	Researcher	Yes
Guidelines as a user of guidelines	NSW	Academic and clinician	No (contacted by telephone)

A copy of the content analysis tool (AGEL Version 1) was sent to the six experts with a specified list of questions. The list included open-ended fields requiring free text responses and questions which required circling the most appropriate response on an ordinal voting scale. The fields included whether there were additional appraisal tools, guidelines or policies that should be considered in developing the AGEL and whether there were gaps; whether there were comments on the overall approach used and how the tool could be improved; rating scales of how well the AGEL would capture notions of equity and socioeconomic determinants in guidelines and how applicable the tool would be to Australian guidelines. Of the six experts, four returned questionnaires with feedback. The remaining two were followed up by telephone and said that they had no specific feedback and that the appraisal tool did not need any adjustment.

The feedback from the four who provided written feedback was then reviewed and another draft of Version 1 was sent by email to those who responded to the first round of consultation, seeking feedback on the revised questionnaire. Consistent with the usual processes for Delphi consultation, it had been intended that there would be up to three rounds of consultation and feedback using updated drafts and questions for experts requesting both structured and open-ended feedback, until all positions were identified. However, no additional comments were received in this second round. To maximise the response rate, a follow-up email was sent to non-responders but no additional responses were received. Subsequently, experts were contacted by telephone and asked if they would prefer to provide advice verbally. Two respondents indicated that they had no further comments and that further detailed feedback was neither necessary nor feasible for them. Two did not respond. Therefore, the Delphi process did not continue to a third round. The limitations of this process will be explored in the Discussion section of this Chapter.

The feedback from the Delphi consultation will be presented in the Results section. The draft of Version 2 was then finalised based on the comments from the initial consultation process. A copy of AGEL Version 2 is shown in Appendix 3. This version was shorter, open-ended fields were removed and terminology used was clarified.

Further refinement of the content analysis tool occurred in 2012 and 2013. The researcher pilot tested the AGEL Version 2 by applying it to 10 guidelines from the Australian Clinical Practice Guidelines Portal published in 2009 to assess feasibility of application, face validity and content validity. In 2013, two medical registrars independently pilot tested five guidelines using the AGEL Version 2. Feedback was sought from these testers. They were sent printed copies of five Australian guidelines from 2012 and were asked verbally whether the questionnaire was easy to use, were there any ambiguities in the AGEL wording, were any changes required and, overall, whether the AGEL was usable to appraise the five guidelines that were presented. The findings are presented in the Results section of this chapter.

Next, the systematic search and comprehensive review of the literature was conducted in 2015, as detailed in Chapter 2, which identified newly available tools such as the PRISMA-Equity 2012 Extension (Welch, Petticrew et al. 2012) and the iCAHE Guidelines quality assessment tool (Grimmer et al. 2014). These had not been available at the time of Version 1.

The feedback from two testers and the findings of the 2015 systematic search and comprehensive review of the literature (Chapter 2) were incorporated into the AGEL Version 3 (shown below and at Appendix 4). The AGEL Version 3 was shorter and had binary variables, ordinal scales or specific choices rather than free text. This version was used to review 74 guidelines on the National Clinical Practice Guidelines Portal from 2010 to 2014 as described in Chapters 4 and 5. The AGEL Version 3 was created as an online version in a REDCap database (Research Electronic Data Capture) hosted by Sydney Local Health District (Harris et al. 2009) so that direct data entry using the content analysis tool could be accessed by any relevant user. The iCAHE instrument (Grimmer, 2014) was added to the online version to allow for collection of data about guideline quality, in order to explore the association between guidelines quality and the inclusion of equity considerations.

3.5.2 Psychometric testing of the Australian Guideline Equity Lens Version 3

To assess inter-rater reliability of the AGEL Version 3, a random sample of 15 guidelines was selected by putting the guideline ID numbers through an online random sample generator. The online Australian Guidelines Equity Lens Version 3 was modified for assessment of inter-rater reliability of the instrument (referred to here as modified AGEL Version 3). This version was entered into the REDCap electronic data capture tool hosted at Sydney Local Health District (Harris et al. 2009). A copy of the online version is at Appendix 4. The modified Version 3 did not include free text fields that were unsuitable for assessment of inter-rater reliability, nor did it include the iCAHE instrument for assessing the overall and methodological quality of clinical practice guidelines (Grimmer et al. 2014). This was because inter-rater reliability of this instrument had already been tested by its developers (Grimmer et al. 2014). The modified Version 3 had 34 fields with response formats including single response multiple choice buttons or checkboxes where more than one choice was possible, with all fields on an ordinal scale.

To assess inter-rater reliability, the researcher and another public health practitioner assessed 15 randomly selected guidelines using the modified AGEL Version 3. The instrument was emailed to the other rater using the REDCap database online survey function so that completion could be done remotely at the desktop with a copy of the guideline. To assess face validity and usability, feedback about the modified AGEL Version 3 was sought from four public health practitioners who pilot tested the instrument with two guidelines. The number of pilot testers chosen was related to resources available for pilot testing and the availability of these pilot public health practitioners, with the limitations arising from this explored in the discussion section of the chapter. Each public health practitioner was asked to appraise two clinical guidelines sent to them in hard copy, with the choice of providing feedback on usability by email or verbally. Specifically, they were asked if the online version was easy to use, whether there was any difficulty in applying it to the guideline, and whether any response fields were difficult to use (usability). They were also asked whether they considered that the response fields picked up the key concepts of equity (face validity) and whether any response fields should be modified to improve this. Concurrent validity of the key response field assessing the visibility of equity and socioeconomic determinants was assessed later with the entire set of guidelines that was analysed and is discussed in Chapter 4.

3.5.3 Statistical methods used to assess inter-rater reliability of the Australian Guidelines Equity Lens Version 3

Inter-rater reliability was assessed by calculating Cohen’s kappa co-efficient with the SPSS Version 22 statistical package (IBM 2013) to assess concordance between raters (Cohen 1960; Bland 2000; McHugh 2012). Use of SPSS was facilitated by a statistical consultant from the University of Melbourne, as listed in the acknowledgements. The researcher determined the statistical testing required and reviewed and analysed the data output from SPSS to interpret the results.

An acceptable weighted kappa co-efficient was defined as 0.6 or above, with kappa below 0.6 taken as indicating inadequate agreement between raters, as was consistent with current practice (McHugh 2012). This level corresponds to “substantial” or “almost perfect” agreement according to Cohen’s classification of the kappa statistic (Cohen 1960). The minimum sample size for a reliability re-test of the questionnaire considering 80% power, 0.05 type 1 error to detect a kappa coefficient of >0.6 in a two-tail single group comparison would have involved reviewing the entire sample of 74 guidelines. However, for resource reasons it was not possible to achieve this sample size. Therefore, a bootstrap non-parametric method was used to calculate 95% confidence intervals on a smaller sample size. This is a technique suitable for small sample sizes where inference about a population can be modelled by resampling the sample data and drawing inferences about the sample from the resampled data (Stine 1989).

The 95% confidence interval (CI) is defined as the range of plausible values for the true kappa co-efficient of which the value obtained is the best estimate. The 95% confidence interval cannot be defined when there is no variability between raters, because statistically it is assumed to be impossible to achieve 100% agreement, and if enough guidelines were rated by enough raters there would eventually be disagreement. In the bootstrap method, the kappa co-efficient was estimated to be exactly zero (0) for cases where one rater always gave the same rating and a 95% CI also could not be calculated in this case.

3.6 Ethical considerations

Ethical issues must be considered and addressed in research and these will now be discussed. Stage 1 of the research involved contacting and providing written questionnaires to experts in the fields of guidelines, evidence-based medicine and health equity, who were selected to be subjects as part of a Delphi panel. It was important that the research conformed with the *National statement of ethical conduct for human research 2007, updated May 2015* (NHMRC 2015b). Stage 1 of the study was approved by the Social and Behavioural Ethics Committee, Flinders University, Project Number 4756. All reporting requirements to that committee have been fulfilled.

The *National Statement* contains a number of research principles. Consistent with the principle of research merit, this dissertation contains the justification for the research (Chapter 1) and demonstrates that the methods used to conduct the research were appropriate to achieving the aims of the proposal (Chapter 3), and were conducted by persons with suitable experience (Chapter 3).

Another important research principle is that the research benefits are greater than any harms. This is a low risk project in that the potential harms to participants from completing a questionnaire which asks for their expertise about a guidelines survey instrument are negligible. Another ethical principle is the need to obtain informed consent. In this study, this was addressed by the research team providing a letter to participants explaining the research, with a Participant Information Sheet that explained what the research would entail and how the information gained would be used. If anyone declined to participate, no further contact was made with them. To provide feedback to the Delphi panel, participants were offered the opportunity to receive copies of papers published in future. This addressed another important ethical principle, namely that research outcomes should be made accessible to participants.

Data security is another important consideration, and the data have been stored according to NHMRC requirements (NHMRC 2015b). Confidentiality of the experts involved has also been maintained. They were asked if they wished to be acknowledged by name in the dissertation, and two gave consent to this and have been acknowledged accordingly.

Stage 2 of the research involved the development of a guidelines appraisal tool and its application to guidelines on a national portal. This involved literature review, document review and paper-based research. There was no human research involved in this stage of the research and therefore institutional ethics committee approval was not required.

Research integrity was an important principle guiding this stage of the research. Hence information identified in the systematic search and comprehensive review of the literature (Chapter 2) has been fully referenced and cited. In addition, all guidelines reviewed from the NHMRC National Clinical Guidelines Portal used in this study are publicly available online and have been fully cited. The iCAHE instrument for guideline quality (Grimmer, 2014), used to appraise guidelines for methodological quality as part of this research, is also a publicly available document and has been fully cited and its use acknowledged.

Finally, it has been argued that ensuring appropriate research dissemination and research translation is an important ethical issue for researchers (Pearn 1995; Institute of Education, University of London, n. d.) As will be shown in Chapter 5, there is a dissemination plan in place for this research to maximise research uptake and guide the translation of research findings into public health policy. This plan was commenced at the time of devising the research. This approach is consistent with what has been described by ethicists as a “translational ethos” where “results must be specifically targeted for particular ends rather than general good” (Maienschein et al. 2008. p. 43). As will be discussed in the dissemination plan, this research was specifically designed to influence public health policy in the area of clinical practice guidelines in Australia, and in particular the NHMRC standards development processes for guidelines. The ways in which this has or will be done are also specified in the dissemination plan. In concluding this section, while the ethical issues are of low risk in this project compared with much other human research, ethical principles and the ethics of research dissemination have been considered in the conduct of this research.

3.7 Results

In this section, details are provided of the results, including the results of feedback from testing the development of three versions of AGEL and its content and psychometric properties.

3.7.1 Australian Guideline Equity Lens Version 1

A copy of the AGEL Version 1 is at Appendix 2. As mentioned earlier in the chapter, of the ten panellists approached, six agreed to participate, four provided written feedback. The limitations of receiving feedback from six of ten panellists will be explored in the discussion section of this chapter. There were two key themes in feedback from the four experts on the Delphi panel who provided the written feedback. The first was that the appraisal tool was complex and lengthy. The experts identified potential pitfalls arising from this, namely that while it might be suitable for research, it would not be suitable for other persons to use, and that it would not be possible to apply the tool to a large number of guidelines because of its length. The second theme was the need to be specific with definitions and to standardise how data is appraised in the instrument to ensure consistency. Specific quotes are as follows:

- *The appraisal tool is suitable for research purposes but would not be suitable for use by others as it is too complex (Expert 1)*
- *Definition of equity needs to be clarified (Expert 2)*
- *The purpose of the appraisal tool needs to be clarified (Expert 3)*
- *The appraisal tool is too complex and too long and needs to be simplified (all)*
- *The appraisal tool is comprehensive for a few guidelines but could not be applied to hundreds of guidelines (Expert 4)*
- *Answers would need to be standardised (Expert 2)*
- *It would be important to focus on known inequity e.g. Aboriginal populations (Expert 4)*

3.7.2 Australian Guidelines Equity Lens Version 2

Based on the feedback described above and using methods detailed earlier in this chapter, the AGEL Version 2 was developed (Appendix 3). Version 2 was shorter, removed detailed questions for content analysis and removed the open-ended fields so that there was more scope for standardising content analysis using the appraisal tool, to improve psychometric properties. There was more clarification of terminology used.

When the AGEL Version 2 was pilot tested by two medical registrars with five guidelines, as detailed in the Methods section of this chapter, the registrars clarified that the AGEL Version 2 was usable and they did not identify specific word changes or ambiguities in the appraisal tool. Using the tool, both testers were able to complete the appraisal of five guidelines, demonstrating its usability. However, one tester noted that it was difficult to use for someone not familiar with the topic area. Both testers commented on the length. Additional feedback from the testers was as follows:

> *Needs to be shorter. Some of the questions repetitive – try to reduce repeat questions. Difficult to understand for someone who does not know the literature. The questionnaire is longer than the guideline*. (Tester 1)
>
> *Some of the questions could not be answered based on the information in the guideline. Cut down the length. Makes you think*. (Tester 2)

3.7.3 Australian Guidelines Equity Lens Version 3

The final version of the fields in the online AGEL Version 3 is included at the end of this Chapter. There are 124 fields divided into six parts, A–F, and if printed, the Lens is seven pages long. The first section of the AGEL (Part A) allowed for collection of information about the guidelines: title, details of the guideline development group, target audience, topic covered, whether the guideline was formally approved by the NHMRC, year of publication and the National Health Priority Area covered. In this section of Part A, information was sought on whether any guideline development frameworks were nominated in the guideline, specifically the AGREE instrument (Sabharwal et al. 2014; Brouwers et al. 2016); the NHMRC standards for guidelines (NHMRC 2011); the National Institute of Clinical Excellence Guidelines (2012); the INCLEN equity in guidelines tool (Dans et al. 2007); World Health Organization standards for guidelines (World Health Organization 2012); PROGRESS framework for systematic reviews (O'Neill et al. 2014) or the ADAPTE framework for adapting guidelines (ADAPTE Collaboration 2009). The framework needed to be specifically mentioned for it to be counted as a positive finding. Explanations of the abbreviations and acronyms used are listed at the beginning of this dissertation.

In Part B, information was recorded about equity and socioeconomic determinants in clinical practice guidelines, which was not derived from another document or framework. The response fields were developed with the advice of the Delphi panel and supervisors in the first instance. Part B was further refined as described above by pilot testing with two registrars and then a further four public health practitioners. Input from the systematic search and comprehensive review of the literature was also used, as described in Chapter 3. In this section, information was collected on the population for which the guidelines would apply, for example, the entire Australian population, those at risk of heart disease, people with a specific condition, or Indigenous Australians. There was one field to identify specific groups who were selected for specific attention in the guidelines. These groups included Indigenous people or communities, children and young people, women, older people, people with disabilities, people from low socioeconomic groups, people with culturally and linguistically diverse background and persons with mental health issues. These groups were identified where relevant, along with information on whether there was consumer or client representation in the guideline development process.

The next important field in Part B covered whether there were specific references to “equity”, “inequality”, “human rights”, “socioeconomic disadvantage” or “fairness” in the guidelines. This allowed for a response of “yes”, “no”, “unsure”, or “not applicable”, followed by a prompt for a free text response of what the specific reference was. Following this, the tool required specification of where in the guideline these references were (e.g. background information, recommendation, in section on gaps or recommendations for further research). This was necessary to allow identification of whether the background information had resulted in a recommendation, a gap, or a recommendation for further research, rather than simply being provided.

The next field was more specific and prompted appraisal of whether social gradient or socioeconomic position informed the guideline recommendations. The final fields in this section covered the focus on equity and socioeconomic determinants in the sources of information used to develop the guidelines, specifically, whether there was mention of the PROGRESS lens for systematic reviews (O’Neill et al. 2014) having been taken into account (noting that the PRISMA-Equity 2012 Extension, its precursor, was available from 2012 [Cochrane Methods Equity Group 2012] and the PROGRESS lens was available from late 2013). The tool also assessed whether gaps in relation to data or research about equity or socioeconomic determinants had been identified in the guidelines and if so, where in the guidelines these gaps were specified. The final field in this section was designed to capture the drivers or rationale for inclusion of equity or socioeconomic determinants in guidelines, where they had been included. This field allowed for specific reasons to be checked. Potential responses included the following: consistent with government or other policy, equity is a stated priority for the guideline development organisation, there is human rights or fairness justification, there is evidence of the impact of social gradient on the health issue/social intervention, civic responsibility, community feedback, other stakeholder requirement, or that the NHMRC or World Health Organization guidelines recommended inclusion of equity in the guidelines. There was also a free text response option for other reasons to be listed.

In Part C, extracted criteria from the INCLEN equity in guidelines tool were shown. These were modified into a format that could be included in the REDCap database questionnaire, with responses “yes”, “no”, “unsure” or “not applicable”. There was some overlap in these fields and with variables in the previous section. The intention of this was to allow assessment of concurrent validity by comparing the response to the fields in the INCLEN lens to similar fields in Part B of the AGEL. (However, as will be discussed later in the Chapter, this was subsequently not possible). The next response field investigated whether the guidelines addressed a priority problem for disadvantaged populations. If this was the case, the user was prompted to specify the population and whether there was a discussion of the burden of disease in that population. Next was a question about whether there was “a reason for the guideline developer to anticipate different effects of intervention in disadvantaged and privileged populations” in terms of the biology of the disease, adherence to treatment or risk factors for the condition. The next field addressed what values were expressed in the guideline and whether the effects of the intervention in the guideline were valued differently by disadvantaged compared with privileged populations and whether there was documented evidence in the guideline of assessment of values through consultations with disadvantaged groups, involvement of caregivers or reference to relevant research. This section of the AGEL ended with two fields that related to the impact or monitoring of guidelines with respect to equity. The first was whether there were plans in the guidelines for assessing the effects of recommendations, including assessment of effects or outcomes in disadvantaged populations. The second was whether there were plans for monitoring disadvantaged groups according to stratifiers such as place of residence, race/ethnicity, occupation, gender, religion, education, socioeconomic status, social network and capital.

Part D was a brief section related to the NHMRC guidelines (NHMRC 1999a) on using socioeconomic evidence in clinical practice guidelines. Specifically, the tool was designed to allow for analysis of whether these NHMRC standards were mentioned in the Australian clinical practice guidelines. Then, as recommended in this NHMRC document, the appraisal instrument prompted an assessment of whether the clinical practice guideline presented an analysis of the clinical issue related to socioeconomic position.

In Part E, issues relating to equity in clinical guidelines were assessed, as specified in the *World Health Organization handbook for guidelines development: Integrating equity, human rights and gender into World Health Organization guidelines* (World Health Organization 2012). This handbook specified six critical areas which should be considered when incorporating equity and a human rights perspective into clinical practice guidelines. These six critical areas allowed for development as part of the appraisal tool for six key questions which could be asked of each guideline as part of the content analysis, with possible responses of “yes”, “no”, “unsure” or “not applicable” for each guideline. For a “yes” response to be noted on the online questionnaire, there needed to be definitive evidence in the guideline that this critical area had been covered. This section of the AGEL was used to appraise whether the guidelines conveyed clear messages with respect to equity, human rights, gender and social determinants; whether there was evidence that the guideline development group included people who understand equity issues; whether there was a declaration of conflict of interest; whether the guideline took into account the potential for differences due to social position; whether there was evidence that the systematic reviews used described the effects of interventions by social gradient. The next field then assessed whether gaps in knowledge and an agenda for future research were outlined, if there was sparse evidence for evidence on equity in relation to the guideline topic.

Finally, in Part F there was an opportunity for free text to be entered relevant to the topic.

3.7.4 Online version of the Australian Guideline Equity Lens Version 3

As discussed in the Methods section of this chapter, the AGEL Version 3 was loaded onto a REDCap (Harris et al. 2007) database to allow more efficient application of the instrument and subsequent data entry by the user than with a paper-based version. Together with the online version of the AGEL, the domains from the iCAHE checklist to appraise methodological quality of guidelines (Grimmer et al. 2014) were also uploaded onto the REDCap database. The iCAHE checklist does not form part of the AGEL but was loaded online with the AGEL so that the methodological quality of the guideline could be assessed and then compared with other parameters identified by the AGEL. For, example associations between methodological quality of guidelines as measured by the iCAHE instrument and the consideration of the needs of Aboriginal and Torres Strait Islander populations could be assessed using data collected by applying both of these instruments and entered online into the REDCap database. The iCAHE instrument included 14 questions, with a score of 1 for a “yes” response and 0 for a “no” response. When responses to these 14 questions were entered onto the REDCap database, a total score could be calculated based on the user’s ratings of clinical practice guideline quality. The questions covered the following parameters: was the guideline readily available in full text; did the guideline provide a summary of its recommendations; were the completion date, the date when literature was included and an anticipated review stated; did the guideline provide an outline of the strategy used to find evidence; was a hierarchy used in the guideline to rank the quality of underlying evidence; was the quality of the evidence underpinning recommendations appraised in the guideline; were the hierarchy and quality of underlying evidence linked to each recommendation in the guideline; were the developers of the guideline, its purpose and target users clearly stated; were the qualifications and expertise of the developer linked with the purpose of the guideline and its end users; and was the guideline readable and easy to navigate (Grimmer et al. 2014). The specific domains from the iCAHE checklist are available in a printout at the end of the online AGEL Version 3, at Appendix 4.

3.7.5 Results of psychometric testing of the Australian Guidelines Equity Lens Version 3

As detailed in the Methods section of this chapter, the online AGEL Version 3 was modified for psychometric testing to include only those fields that could be used for calculating inter-rater reliability. A printout of the instrument is provided at Appendix 5. In this section, the results of the psychometric testing of the instrument are presented.

Kappa co-efficient values and 95% confidence intervals for each field in the modified AGEL Version 3 are shown in Table 5. This shows that of the 34 fields in the modified AGEL Version 3, there were 51 potential responses for which kappa co-efficients could be estimated, with 27 of these also having 95% CIs calculated using the bootstrap method. Another 17 fields had kappa values of 1, but confidence intervals could not be calculated because there was no variability between raters. Where 95% CIs could not be calculated, the value is shown as “n/a”.

Of the 51 potential response fields in the instrument, there was high correlation between raters in 17 fields, with kappa values above 0.6 where 95% CIs could be calculated and confidence intervals did not cross 0. In key fields that related to the appraisal of equity, socioeconomic determinants and consideration of Aboriginal and Torres Strait Islander populations (Table 5*)* there was a statistically significant concordance between raters. These are highlighted in italics in Table 5.

There was poor correlation between raters for seven sets of questions based on parameters in a previous guideline equity lens, the INCLEN equity in guidelines tool (Dans et al. 2007). These are highlighted in bold in Table 5. ("Is there a reason for the guideline developers to anticipate different effects of the intervention in disadvantaged and privileged populations? Is there a discussion of the differences between disadvantaged and privileged populations in terms of any of the adherence to treatment compared to privileged populations? Are the effects of the intervention valued differently by disadvantaged compared to privileged populations?"). These were included in the AGEL Version 3 and analysed. However, as will be discussed in the Discussion section of this chapter, because of their poor psychometric properties, including poor usability and reliability, these responses are reported in the results but interpreted with caution.

The results show, overall, that apart from the fields derived from the INCLEN equity in guidelines tool, there was acceptable inter-rater reliability in key fields within the modified AGEL Version 3, noting the small sample size and limitations which will be discussed later in this chapter.

Table 5: Kappa values and 95% confidence intervals for each of the fields on the modified AGEL Version 3 to assess inter-rater reliability

Field	**Kappa estimate**	**95% CI***
Has any other guideline development framework, tool been used in the development of this guideline?	1.00	n/a
If so, which? (choice=AGREE instrument)	1.00	n/a
If so, which? (choice=NHMRC guidelines for guidelines)	1.00	n/a
If so, which? (choice=Other)	0.63	0.00, 1.00

Is the primary audience:	1.00	n/a
Please check the relevant box(es) if any of the following groups are given specific attention? (choice=Indigenous people/communities)	1.00	n/a
Please check the relevant box(es) if any of the following groups are given specific attention? (choice=Children and young people)	0.86	0.00, 1.00
Please check the relevant box(es) if any of the following groups are given specific attention? (choice=Women)	0.66	–0.10, 1.00
Please check the relevant box(es) if any of the following groups are given specific attention? (choice=Older people)	0.81	0.00, 1.00
Please check the relevant box(es) if any of the following groups are given specific attention? (choice=People from low socioeconomic groups)	0.84	0.00, 1.00
Please check the relevant box(es) if any of the following groups are given specific attention? (choice=People from culturally and linguistically diverse backgrounds)	0.57	–0.1, 0.86
Please check the relevant box(es) if any of the following groups are given specific attention? (choice=Persons with mental health issues)	0.71	0.00, 1.00
Is consumer/client representation described in the guideline development process?	0.76	0.00, 1.00
Are there specific reference(s) in the guideline to the need to address inequity, inequality, human rights, socioeconomic disadvantage or fairness?	1.00	n/a
In which sections of the guideline are there references to inequity/inequality/fairness/socioeconomic disadvantage/socioeconomic position? (choice=Background information or in literature review)	1.00	n/a
In which sections of the guideline are there references to inequity/inequality/fairness/socioeconomic disadvantage/socioeconomic position? (choice=Recommendation/interventions/guidance)	1.00	n/a
In which sections of the guideline are there references to inequity/inequality/fairness/socioeconomic disadvantage/socioeconomic position? (choice=Identification of gaps or recommendations for further research)	0.00	n/a
Has evidence on social gradient or socioeconomic position	1.00	n/a

informed the guidance recommendations?		
Have gaps in relation to data or research on social gradient and equity been identified in the guidelines?	1.00	n/a
If yes, where? (choice=Guideline literature review)	1.00	n/a
If yes, where? (choice=Guidance section/recommendations)	0.63	0.00, 1.00
If yes, where? (choice=Summary/conclusions)	0.00	n/a
If yes, where? (choice=Specific section relating to gaps/further research)	0.63	0.00, 1.00
If there is evidence of equity being considered or addressed in the guideline, what has been documented in the guidelines as the reason(s), rationale for including equity in these guidelines (if at all)? (choice=Consistent with government or other policy)	0.00	n/a
If there is evidence of equity being considered or addressed in the guideline, what has been documented in the guidelines as the reason(s), rationale for including equity in these guidelines (if at all)? (choice=Equity is stated a priority for the guideline	1.00	n/a
If there is evidence of equity being considered or addressed in the guideline, what has been documented in the guidelines as the reason(s), rationale for including equity in these guidelines (if at all)? (choice=Human rights or fairness justification])	0.00	n/a
If there is evidence of equity being considered or addressed in the guideline, what has been documented in the guidelines as the reason(s), rationale for including equity in these guidelines (if at all)? (choice=Evidence of impact of social gradient on the	1.00	n/a
If there is evidence of equity being considered or addressed in the guideline, what has been documented in the guidelines as the reason(s), rationale for including equity in these guidelines (if at all)? (choice=Community requirement/feedback)	0.00	n/a
If there is evidence of equity being considered or addressed in the guideline, what has been documented in the guidelines as the reason(s), rationale for including equity in these guidelines (if at all)? (choice=Other)	0.00	n/a
Do the recommendations in the guidelines address a priority	0.76	0.42, 1.00

problem for disadvantaged populations?		
Is there a reason for the guideline developers to anticipate different effects of intervention in disadvantaged and privileged populations?	0.43	0.00, 0.75
If yes, if there a discussion of the differences between disadvantaged and privileged populations in terms of any of the following? (choice=biology of the disease)	0.76	–0.52, 0.00
If yes, if there a discussion of the differences between disadvantaged and privileged populations in terms of any of the following? (choice=adherence)	–0.12	–0.52, 0.00
If yes, if there a discussion of the differences between disadvantaged and privileged populations in terms of any of the following? (choice=risk factors for the condition)	0.57	–0.11, 0.86
Are the effects of the intervention VALUED DIFFERENTLY by disadvantaged compared to privileged populations? (choice=Yes)	–0.10	–0.57, 0.00
Are the effects of the intervention VALUED DIFFERENTLY by disadvantaged compared to privileged populations? (choice=No)	0.00	n/a
Are the effects of the intervention VALUED DIFFERENTLY by disadvantaged compared to privileged populations? (choice=Unsure)	–0.13	–0.58, 0.00
Is there evidence of assessment of VALUES through any of the following (about what the group might value)? (choice=consultations with disadvantaged groups)	0.81	0.00, 1.00
Is there evidence of assessment of VALUES through any of the following (about what the group might value)? (choice=involvement of caregivers)	1.00	n/a
Is there evidence of assessment of VALUES through any of the following (about what the group might value)? (choice=reference to relevant research)	0.57	–0.10, 0.86
Is there evidence of assessment of VALUES through any of the following (about what the group might value)? (choice=no evidence that values are assessed)	0.59	–0.03, 0.87
Is specific attention given to minimising barriers to implementation in disadvantaged populations or strategies to overcoming these barriers? (choice=Yes)	1.00	n/a

Is specific attention given to minimising barriers to implementation in disadvantaged populations or strategies to overcoming these barriers? (choice=No)	1.00	n/a
Are the NHMRC guidelines on using socioeconomic evidence in clinical practice guidelines referenced?	1.00	n/a
Does the guideline present an analysis of the clinical issue related to socioeconomic position?	0.84	0.00, 1.00
Does the guideline present an analysis of the clinical issue related to socioeconomic position?	0.84	0.00, 1.00
Does the guideline convey clear messages with respect to equity, human rights, gender and social determinants?	0.57	0.00, 1.00
Is there evidence that the guideline development group includes individuals who would have an understanding of equity issues?	0.63	0.23, 0.88
Is there a declaration of conflict of interest?	0.87	0.49, 1.00
Does the guideline take into account the potential for differences in uptake and benefits as a function of social position?	0.85	0.00, 1.00
Is there evidence that the systematic reviews used to inform guideline development explicitly describe the potential effect of interventions not only on the population as a whole but across the social gradient?	1.00	n/a

* 95% confidence intervals are calculated using non-parametric bootstrapping. They cannot be calculated for kappa scores of exactly 0 or 1.

** Fields are bolded where the kappa co-efficient was less than 0.6 or there was negative correlation between the two raters

3.7.6 Face validity, acceptability and usability of the Australian Guideline Equity Lens Version 3

Earlier in this chapter, the methods of obtaining feedback from the four public health practitioners who pilot tested the modified AGEL Version 3 to assess its usability were described. This section reports the results of this testing. The pilot testers found the online appraisal tool format easy to use so that it did not need significant modification. All testers were able to complete their allocated guideline appraisals using the online version of the AGEL Version 3. Two testers indicated that some fields were repetitive, although they did not specify which. Two testers also commented that the fields derived from the INCLEN equity tool were difficult to complete, especially when the guidelines did not explicitly state the details required in completing the field and inference was required, for example, “e.g. are the effects of the intervention valued differently by disadvantaged compared to privileged populations?”. All testers indicated that the online AGEL Version 3 assisted in identifying whether equity or socioeconomic determinants were considered in clinical guidelines and that it captured related issues, suggesting the acceptability (face validity) and usability of the modified AGEL Version 3 overall.

The final version of the AGEL Version 3 is on the following pages. The findings of Stage 1 of the research will be discussed after these pages.

THE VISIBILITY OF “EQUITY” IN CLINICAL PRACTICE GUIDELINES

Australian Guidelines Equity Lens

Version 3

PART A: Background information about the guideline

1. What is the title of the guideline?

2. What is (are) the name of the guideline development group(s)?

2a Who is the target audience for the guideline? (If this is specifically stated in the guideline). Chose as many as appropriate

○ Medical Specialists
○ General Practitioners
○ Other medical practitioners
○ Nurses
○ Dentists
○ Exercise physiologists
○ Allied health not otherwise stated
○ Medical physicists
○ Optometrists
○ Pharmacists
○ Radiographer/Sonographer
○ Psychologist
○ Physiotherapist
○ Podiatrist
○ Social worker
○ Speech pathologist
○ First aiders
○ Aboriginal Health Workers
○ Aged care workers not otherwise stated
○ Drug and alcohol workers
○ Occupational therapist
○ Other
○ None stated previously

2b Who is the target audience for the guideline? (presumed / assumed if not specifically stated. Chose as many as appropriate

○ Medical Specialists
○ General Practitioners
○ Other medical practitioners
○ Nurses
○ Dentists

- ○ Exercise physiologists
- ○ Allied health not otherwise stated
- ○ Medical physicists
- ○ Optometrists
- ○ Pharmacists
- ○ Radiographer/Sonographer
- ○ Psychologist
- ○ Physiotherapist
- ○ Podiatrist
- ○ Social worker
- ○ Speech pathologist
- ○ First aiders
- ○ Aboriginal Health Workers
- ○ Aged care workers not otherwise stated
- ○ Drug and alcohol workers
- ○ Occupational therapist
- ○ Other
- ○ None stated previously

3. Which of the following is the most relevant description of the primary guideline development groups(s)? [circle appropriate categories]
    - ○ Multidisciplinary non-government organisation (eg NHF, Cancer Council)
    - ○ NHMRC
    - ○ Other Federal Government body
    - ○ State health government
    - ○ Local health service
    - ○ Other government department
    - ○ Local government
    - ○ Condition specific group
    - ○ NACCHO / State affiliate / Aboriginal Community Controlled Organization
    - ○ Medical College
    - ○ Specialty Society
    - ○ Nursing College
    - ○ Other health professional organisation
    - ○ Consumer organisation
    - ○ Other. Please specify:

____

3a Which of the following is the most relevant description of any other guideline development groups(s)? [Circle the best one / or as many as apply?]

- Multidisciplinary non-government organisation (eg NHF, Cancer Council)
- NHMRC
- Other Federal Government body
- State government
- Local health service
- Other government department
- Local government
- Aboriginal Community Controlled Organisation
- Medical College
- Specialty Society
- Nursing College
- Other health professional organisation
- Consumer organisation
- Other. Specify:

____

Complete the following information (sourced from the NHMRC Clinical Practice Guidelines Portal, as determined by the portal administrator(s).

4. Condition:

5. Developer:

6. Is the guideline NHMRC approved? (Y/N)

7. Year of publication:
    - 2010
    - 2011
    - 2012
    - 2013
    - 2014

8. In which National Health Priority Area is this guideline?
    - Cancer control
    - Cardiovascular health
    - Injury prevention and control
    - Mental health
    - Diabetes mellitus
    - Asthma
    - Arthritis and musculoskeletal conditions
    - Obesity
    - Dementia

9. Has any other guideline development framework, tool been used in the development of this guideline? (Yes, no, unsure, not applicable)

10. If so, which:

- ○ AGREE instrument [Yes, no, unsure, not applicable]
- ○ NHMRC guidelines for guidelines [Yes, no, unsure, not applicable]
- ○ NICE guidelines [Yes, no, unsure, not applicable]
- ○ INCLEN equity guideline [Yes, no, unsure, not applicable]
- ○ WHO guidelines [Yes, no, unsure, not applicable]
- ○ PROGRESS/PROGRESS plus for systematic reviews
- ○ ADAPTE process for adapting guidelines
- ○ Other

11. Is the primary audience:

    - ○ Australian and international?
    - ○ Australian?
    - ○ State or jurisdiction-based?
    - ○ Other: ____

PART B: SUMMATION OF VISIBILITY OF EQUITY IN GUIDELINES

12. Describe/state the population(s) for which the guideline would apply (e.g. entire Australian, population, "those at risk of heart disease", Indigenous Australians, people with a specific condition).

____

13. Please check if any of the following population groups are given specific attention?
    - ○ Aboriginal and Torres Strait Islanders
    - ○ Children and young people
    - ○ Women
    - ○ Older people
    - ○ People with disabilities
    - ○ People from low socioeconomic groups
    - ○ People from culturally and linguistically diverse backgrounds
    - ○ Other:_____________________________________

14. Is consumer/client representation described in the guideline development process? [Yes, no, unsure, not applicable]

15. Are there specific reference(s) in the guideline to the need to address inequity, inequality, human rights, socioeconomic disadvantage or fairness? [Yes, no, unsure, not applicable]

    a. If yes, specify details of this reference(s).

    ____

b. In which sections of the guideline are there references to inequity/inequality/fairness/socioeconomic disadvantage/socioeconomic position in: (check as many as are appropriate)

- ○ Background information or in literature review?
- ○ Recommendation/interventions/guidance?
- ○ Identification of gaps or recommendations for further research?
- ○ Other?

16. Has evidence on social gradient or socioeconomic position informed the guidance recommendations? [Yes, no, unsure, not applicable]

17. Is there mention of the PROGRESS lens for systematic reviews being taken into account into evidence synthesis? [Yes, no, unsure, not applicable]

18. Have gaps in relation to data or research h on social gradient and equity been identified in the guidelines? [Yes, no, unsure, not applicable]

18a If yes, where: (check as many as appropriate)

- ○ Guideline literature review
- ○ Guidance section/recommendations
- ○ Summary/conclusions
- ○ Specific section relating to gaps/further research
- ○ Other

19. If there is evidence of equity being considered in the guideline, what has been documented in the guidelines as the reason(s), rationale for including equity in these guidelines (if at all)? (check all that are applicable)

- ○ Consistent with government or other policy
- ○ Equity is stated a priority for the guideline development organisation
- ○ Human rights or fairness justification made
- ○ Evidence of impact of social gradient on the health issue/social intervention
- ○ Civic responsibility
- ○ Community requirement/feedback
- ○ Other stakeholder requirement
- ○ NHMRC guidelines on socioeconomic determinants
- ○ *WHO handbook for guideline development* – equity chapter
- ○ Other:_____________

PART C: APPRAISAL OF CRITERIA USING THE INCLEN EQUITY LENS (Dans et al. with additional information from Mizen et al.)

20. Do the recommendations in the guidelines address a priority problem for disadvantaged populations? [Yes, no, unsure, not applicable]

20a. If yes, is there discussion of the burden of disease in disadvantaged populations)? [Yes, no, unsure, not applicable]

20b If so, which population (s)?

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21. Is there a reason for the guideline developers to anticipate different effects of intervention in disadvantaged and privileged populations? [Yes, no, unsure, not applicable]

21a. If yes, is there discussion of the differences between disadvantaged and privileged populations, in terms of

- ○ biology of the disease?
- ○ adherence?
- ○ risk factors for the condition?

22. Are the effects of the intervention *valued differently* by disadvantaged compared to privileged populations? [Yes, no, unsure, not applicable]

23. Is there evidence of assessment of values through any of the following (about what the group might value):
    - ○ consultations with disadvantaged groups
    - ○ involvement of caregivers
    - ○ reference to relevant research
    - ○ No evidence values are assessed

24. Is specific attention given to minimising barriers to implementation in disadvantaged populations or strategies to overcoming these barriers? [Yes, no, unsure, not applicable]
    a. If yes, please specify:

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____

25. Do plans for assessing the impact of the recommendations include assessing impact /outcome in disadvantaged populations? [Yes, no, unsure, not applicable]

25a. If yes, are there plans for monitoring disadvantaged groups according to any of the following (check which apply)

- ○ place of residence?
- ○ race/ethnicity?
- ○ occupation?
- ○ gender?
- ○ religion?
- ○ education
- ○ socioeconomic status?
- ○ social network and capital?

PART D: NHMRC guidelines on using socioeconomic evidence in clinical practice guidelines

26. Are the NHMRC guidelines on using socioeconomic evidence in clinical practice guidelines referenced? [Yes, no, unsure, not applicable]

27. Does the guideline present an analysis of the clinical issue related to socioeconomic position? [Yes, no, unsure, not applicable]

PART E: WHO Handbook for guideline development: Integrating equity, human rights and gender into WHO guidelines, 2012

28. Does the guideline convey clear messages with respect to equity, human rights, gender and social determinants? [Yes, no, unsure, not applicable]

29. Is there evidence that the guideline development group includes individuals who would have an understanding of equity issues? [Yes, no, unsure, not applicable]

30. Is there a declaration of conflict of interest [Yes, no, unsure, not applicable]

31. Does the guideline take into account the potential for differences in uptake and benefits as a function of social position? [Yes, no, unsure, not applicable]

32. Is there evidence that the systematic reviews used to inform guideline development explicitly describe the potential effect of interventions not only on the population as a whole but across the social gradient? [Yes, no, unsure, not applicable]

33. Where information on equity is sparse in evidence, are conditional recommendations made, outlining key gaps in knowledge and an agenda for future research? [Yes, no, unsure, not applicable]

PART F: Additional comments regarding Part A to E

34. Is there any other information that is relevant or comments?

    ____

3.8 Discussion

In this chapter, the development of an online content analysis tool, the AGEL Version 3, for assessing the visibility of equity and socioeconomic determinants in Australian clinical practice guidelines has been described (Stage 1 of the research). As will be described in the next chapter, this online content analysis tool was subsequently used to appraise guidelines on the National Clinical Practice Guidelines Portal (Stage 2). Following a systematic search and comprehensive review of the literature, a policy Delphi process with content experts was used in the development of the content analysis tool. Psychometric properties of the AGEL Version 3 such as acceptability, face validity usability and inter-rater reliability have been assessed as generally sound. In particular, inter-rater reliability of the instrument was high in fields which directly appraised the presence of equity or socioeconomic determinants in clinical practice guidelines or which appraised whether disadvantaged populations were considered, although some fields (adapted from an existing guideline equity lens), had poor correlation between raters. Pilot testing also confirmed that the instrument was usable and acceptable to likely users. It is recognised, however, that the AGEL Version 3 is still at an early stage of development compared with other guideline appraisal tools, some of which, such as the most recent AGREE instrument (Don-Wauchope et al. 2012), have been in development for ten years or more. The AGREE instrument has had testing and retesting in different settings with multiple users and multiple modifications to evaluate and improve its psychometric properties (Brouwers et al. 2010a, 2010b, 2010c). Future use of the AGEL Version 3 would benefit from more development and more extensive psychometric testing with different users, as has occurred with the other appraisal instruments mentioned.

In this study, inter-rater reliability of the AGEL was assessed for key fields in the instrument by calculating the correlation between the scores from two observers using the kappa coefficient (Cohen 1960; Bland 2000; McHugh 2012). For a content analysis tool such as the AGEL, inter-rater reliability is a key psychometric property, particularly if such a tool or a modification of it is to be used by guideline developers or by those appraising guidelines for approval or funding (such as the NHMRC). The AGEL fields generally demonstrated good inter-rater reliability when tested with two raters, except in relation to some fields from an existing guideline equity lens (the INCLEN equity in guidelines tool). These fields also had poor usability, as determined by pilot testing, hence this low usability would contribute to poor inter-rater reliability. Accordingly, in Chapter 4, while results of these fields from the INCLEN equity in guidelines tool are presented for completeness, interpretation of the findings related to them is limited.

Further, in general terms, because of the small sample size of guidelines tested for inter-rater reliability, the kappa co-efficient results are interpreted with caution, even though a bootstrap method (for small sample sizes) was specifically chosen for analysis, allowing for significance testing. In fields where kappa was low and there was poor agreement between raters, confidence intervals were wide, precluding any definitive quantitative interpretation of the kappa results for inter-rater reliability in these fields.

In developing this appraisal instrument, it was important that the AGEL would be valid, usable and acceptable to users of the instrument. As mentioned in the introduction, a systematic search and comprehensive review of the literature was undertaken, followed by the preparation of several drafts of the AGEL, to refine the content and maximise the validity of the instrument. In addition, a policy Delphi consultation with experts was conducted to improve its validity. In the methods section, strategies were described to engage and retain ten expert panellists. For reasons explained in the Introduction, this number of panellists was determined to be optimal and feasible for such a Delphi consultation by the candidate and supervisors. In this research, six panellists subsequently participated in the Delphi consultation, and this was a potential limitation as it may have impacted on the range of input into the development of the AGEL and the validity of the instrument. Further, while the policy Delphi process had been intended to progress to three rounds of consultation, which is a standard approach for policy Delphi consultations described in the literature (Linstone and Turoff 2002; Skulmoski and Hartman 2007), this was not possible. Specifically, there was difficulty in improving response rates to retain the experts in the Delphi consultation process to complete the third round of consultation, despite using recommended methods described earlier in this chapter. This was with a view to circulating a final revision of the instrument to the Delphi panel. However, the consultation process was completed in the second round, with panellists who were still involved indicating that there was no requirement to review further drafts. The inability to complete three rounds of consultation was a methodological limitation of this research which may have diminished the instrument’s validity. On the other hand, it is of relevance that the experts who were still involved in the second round responded positively that the AGEL was acceptable and appropriate, and that no further comment was therefore required. In addition, the subsequent pilot testing and psychometric testing of the instrument has demonstrated the usability, acceptability and face validity of the AGEL through other methods, as detailed in the methods section of this chapter and which will be discussed further in the following paragraphs.

For this study, and for reasons explained earlier in the chapter, the most relevant aspect of validity testing was face validity. Face validity refers to an instrument appearing to measure what it claims to measure (Gaber 2010). Assessment of face validity was the most practical assessment that could be made with a complex and detailed survey instrument such as the AGEL Version 3, given that it measures a number of parameters and has 124 fields. (Gravetter and Forzano 2009). Pilot testing confirmed face validity, although a limitation was the small sample size resulting from resource constraints which restricted the number of pilot testers available. This meant that feedback could only be analysed qualitatively and in a general manner. Notwithstanding, the feedback confirmed that the four pilot testers believed the instrument would capture equity and socioeconomic determinants in clinical practice guidelines adequately. It is suggested that further validity testing is warranted in other settings, with other users and with larger sample sizes, if the instrument is to be used in future or if is to be used more widely, as has occurred with other guidelines appraisal instruments. This would extend the assessment of validity of the AGEL and if possible, demonstrate this psychometric property quantitatively.

This instrument included fields from the only other guideline equity lens available, the INCLEN Lens (Dans et al. 2007), with the objective of exploring concurrent validity between it and the AGEL. It had been intended to compare relevant fields in the modified AGEL Version 3 with similar fields in the INCLEN equity in guidelines tool to assess concurrent validity; that is, whether scores from the new instrument were directly related to scores from an existing instrument. Because of difficulties in interpreting the fields from the INCLEN equity in guidelines tool, it was not feasible in this study to assess concurrent validity. Because there has been no psychometric testing published for the INCLEN equity in guidelines tool, there is no comparison data from a “gold standard” with which to compare the AGEL Version 3. In this study, acceptability of the instrument was assessed through pilot testing, because this was most feasible. Usability, the ease with which the AGEL could be administered and interpreted by users, was also assessed by pilot testing and the online version of the AGEL Version 3 was assessed by four testers as being very usable, except for the fields derived from the INCLEN equity in guidelines tool. Usability of the instrument was improved in different versions over time, by rounds of pilot testing.

In concluding this chapter, the psychometric properties of the AGEL were sound for assessing the visibility of equity, socioeconomic determinants and consideration of disadvantaged groups in clinical practice guidelines, noting the methodological limitations in instrument development and psychometric testing which have been discussed in this chapter. Further development and psychometric testing of the AGEL over a number of iterations and with different user groups, as has occurred with other guidelines appraisal instruments such as the AGREE instrument for appraisal of quality of guidelines, would improve it. The psychometric properties of AGEL are relevant to the interpretation of findings and subsequently to the policy implications of the research. The validity and reliability of the assessment tool are relevant to ensuring that the collection of data is accurately captured via the AGEL so that aggregate data resulting from the use of the appraisal tool on a set of guidelines, as detailed in Chapter 4, reliably reflects the true visibility of equity, socioeconomic determinants and consideration of disadvantaged populations in these guidelines.

Chapter 4: Content analysis using the Australian Guidelines Equity Lens (Stage 2)

In this chapter, Stage 2 of the research undertaken to identify and assess guidelines on the NHMRC National Clinical Guidelines Portal, using the AGEL is described, including how the sampling frame was determined and the inclusion and exclusion criteria.

4.1 Objectives

The objectives of this stage of the study were, first, to determine the visibility of “equity”, “inequity” and “socioeconomic determinants” in clinical practice guidelines on the Australian clinical practice guidelines portal over the period 2010–2014 and then to assess whether and how equity was given emphasis in the guidelines, including consideration of disadvantaged populations. Other objectives were to identify which policies were stated as influencing the inclusion of equity considerations in guidelines where equity or socioeconomic evidence were visible and, in particular, to assess whether the NHMRC framework *Using socioeconomic evidence in clinical practice guidelines* was used to inform its development (NHMRC 1999a). A further objective was to determine the characteristics of Australian guidelines which placed emphasis on equity and socioeconomic determinants and whether these were associated with better guideline quality, as measured by the iCAHE instrument (Grimmer et al. 2014).

4.2 Methods

4.2.1 Sampling frame

For the reasons explained in Chapter 1, this study only considered guidelines in the National Health Priority Areas. The sampling frame was all Australian clinical practice guidelines on the NHMRC Clinical Practice Guidelines Portal, published between 2010 and 2014, in the National Health Priority Areas. These nine areas were cancer control, cardiovascular health, injury prevention and control, mental health, diabetes mellitus, asthma, arthritis and musculoskeletal conditions, obesity, and dementia (Australian Institute of Health and Welfare 2000.)

4.2.2 Guidelines inclusion and exclusion criteria

Management of acute incidents or conditions and guidelines relating to single interventions (individual procedures, medications, diagnostic tests) were not included. This is because these individual procedures, tests, and medications may be short-term or single events, and in some cases may be done by proceduralists who are not involved in the ongoing care of patients. From a clinical perspective, longer term equity considerations are unlikely to be practical in such acute situations or in relation to a single medication or test at one point in time. Guidelines documents that incorporated a compendium of guidelines were not considered in this analysis for feasibility reasons, because some parts would have been in National Health Priority Areas while other parts would not. In addition, many documents included as “guidelines” on the portal state “collaborating authors” as the primary guideline developer. However, such journal articles from *Australian Family Physician* are not collaborative clinical practice guidelines. Given the above considerations, the following criteria were used to include or exclude guidelines from the study sample:

Guidelines were *excluded* from the study if they:

- were related to resuscitation, emergency treatment or first aid;
- were related to a single medication, interventional procedure, diagnostic test or therapy type (e.g. a type of radiotherapy, a type of medication);
- encompassed a range of guidelines on different topics (e.g. *Guidelines for preventive activities in general practice*);
- were clinical pathway/clinical protocols;
- were “guidelines” from *Australian Family Physician* which were journal articles rather than clinical practice guidelines;
- were position statements that did not include a literature review.

Guidelines were *included* in the study if they met all the following criteria:

- listed on the NHMRC Clinical Practice Guidelines Portal as being published between 2010 and 2014; AND
- in a National Health Priority Area as listed above; AND
- produced under the auspices of a medical specialty association, relevant specialist society, public or private health organisation, non-government agency, university affiliation or government agency at a Federal or State level for use in Australia; AND
- did not fit any of the exclusion criteria.

For guidelines that had been developed and then reviewed within the 5-year study period, the most recent (updated) version of the guideline was used for assessment and older versions were excluded.

To determine systematically which guidelines would be excluded and the reasons for this, lists of all guidelines for each year were produced from the portal using the advanced search function on 29 October 2015. The function allowed sorting by year of publication. All guidelines on each list were then allocated a number. The candidate reviewed each of the 558 guideline titles to identify documents that were likely to be within the nine National Health Priority Areas. This yielded 203 documents, which were then sourced to check which guidelines met the inclusion criteria and which should be excluded. Each document was sourced through the Clinical Practice Guideline Portal Links and printed for review.

A REDCap (Research Electronic Capture) database (Harris et al. 2009) was created in which a number was allocated and a list of codes applied to identify the reason for inclusion or exclusion of each of the 558 guidelines. Where guidelines could not be sourced through portal links, an internet search engine was used to source the guideline. If the full text guideline could not be sourced by either method, it was classified as excluded and the reason noted. Frequencies of reasons for exclusion and number of guidelines included in the study were tabulated using the statistics function of the REDCap database.

4.2.3 Data collection using the Australian Guidelines Equity Lens Version 3

As described in Chapter 3, an online database and questionnaire was developed, based on the fields in the Australian Guidelines Equity Lens Version 3 in the

REDCap database created for the purpose by the candidate. Creation of fields in the online database, using question formats available for the database, resulted in some minor modifications to the structure for fields and responses from Version 3. The iCAHE instrument questions for methodological quality (Grimmer et al. 2014) were also uploaded with the online version of the AGEL Version 3 onto the REDCap database to allow for systematic and quantitative assessment of the overall methodological quality of each of the guidelines. The result of this was an online questionnaire version of the Australian Guidelines Equity Lens Version 3 and additionally the iCAHE instrument (Grimmer, 2014). One online questionnaire was then completed for each of the 74 guidelines which met the inclusion criteria, by appraising the content of each guideline using the online AGEL Version 3. A breakdown of how the 74 guidelines were selected from 558 guidelines from the NHMRC Australian Clinical Guidelines Portal is presented in the Results section of this Chapter and is shown in Figure 1.

4.2.4 Data analysis and interpretation

Frequencies of responses for each of the variables of data collected in the REDCap online database were tabulated. Chi-squared (Fisher's exact test) and univariate analysis were used to identify significant associations between variables by exporting data from the REDCap electronic data capture tool to SPSS Version 22 (IBM 2013). In particular, the association between methodological quality, as determined by the iCAHE instrument (Grimmer et al. 2014), and the inclusion of equity in guidelines was explored using univariate analysis.

4.3 Results

In this section, results of the appraisal of guidelines using the AGEL will be presented (Stage 2). First, key results arising from Stage 2 will be summarised. Detailed analysis of results of Stage 2 will be presented in subsequent sections.

4.3.1 Summary of key findings from Stage 2

In Stage 2 of this research, a number of key findings were identified which are summarised in this section and detailed later in this chapter. In total, 74 guidelines were assessed using the AGEL, all of which were published on the NHMRC Clinical Practice Guidelines Portal between 2010 and 2014 in National Health Priority Areas. Of the 74 guidelines in the sample, 23 (31.1%) contained specific references to equity and/or socioeconomic disadvantage, but this was mentioned more frequently in the background or literature section of the guidelines than in the recommendations. Very few (n=12) guidelines identified gaps for further research and only two of them specifically mentioned equity (n=1) or inequity (n=1). Clinical practice guidelines which had been approved by the NHMRC and which documented consumer input or referenced NHMRC standards for guidelines development were significantly more likely to be associated with inclusion of equity or socioeconomic determinants in the guideline. In the 23 guidelines where equity or socioeconomic determinants were considered, the rationale in most cases (n=21) was related to the impact of socioeconomic factors on health. No guideline made reference to human rights, or a rights perspective.

The overall quality of the guidelines, as assessed by the iCAHE guideline assessment tool (Grimmer, 2014), was variable. There was no significant association between guidelines that mentioned equity or socioeconomic determinants and methodological quality of the guideline, using the score obtained by applying the iCAHE instrument to each guideline. No guidelines referred to the NHMRC (1999a) document, *Using socioeconomic evidence in clinical practice guidelines* (Aldrich et al. 2003)

Aboriginal and Torres Strait Islander populations were given specific attention in 33 of the 74 guidelines (44.6%). Guidelines were significantly more likely to consider Aboriginal and Torres Strait Islander populations if they were approved by the NHMRC or where there was consumer input into guideline development. Aboriginal and Torres Strait Islander populations were not considered in three of the 15 guidelines that were formally endorsed by the NHMRC. There was specific reference to equity in only one of the guidelines approved by the NHMRC and reference to socioeconomic determinants in eight of the 15 guidelines. Six guidelines referred to socioeconomic determinants, only nine of the 26 guidelines relating to cancer gave specific attention to Aboriginal and Torres Strait Islander populations and only six to culturally and linguistically diverse populations. Mental health guidelines were better in this regard, with 11 of 15 mental health guidelines specifically considering Aboriginal and Torres Strait Islander communities.

These findings have implications for public health policy and for future research, as will be discussed in Chapter 5.

4.3.2 Guidelines included and excluded from the study sample

There were 558 guidelines listed on the Australian Clinical Practice Guidelines Portal with a publication date between 2010 and 2014 at 29 October 2015. Of these, 74 met the criteria for the study as shown in Figure 1 below.

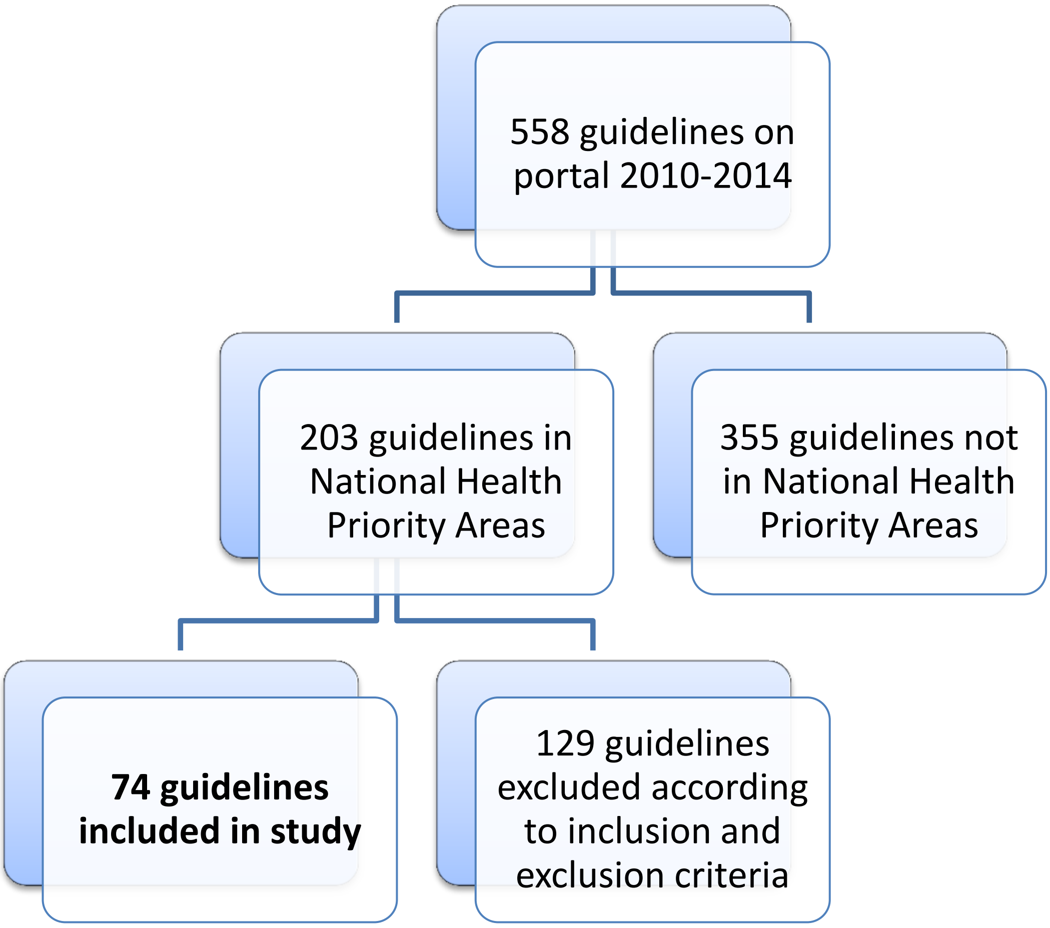

Figure 1: Selection of guidelines for the study sample from 558 guidelines on the National Health and Medical Research Council Australian Clinical Practice Guidelines Portal, 2010–2014

As can be seen in Figure 1, 355 guidelines were excluded because they were not in one of the nine National Health Priority areas. Of the remaining 203 guidelines, 74 guidelines (36.4% of the 203 guidelines) met the inclusion criteria and were included in the study sample. The reasons for exclusion of the other 129 documents are set out in Table 6.

Table 6: Reason for exclusion of 129 guidelines published between 2010 and 2014 from the study

Reason for exclusion from study sample	Number excluded
Document was a journal review article, not a clinical practice guideline	61
Document was a clinical protocol or clinical pathway	19
Unable to source document through the portal link or internet search	14
Guideline topic was a single diagnostic test, procedure or therapy	14
Guideline topic was about first aid/resuscitation/acute emergency	9
Document was a position statement, not a guideline	8
Document was not for clinicians	2
Document was a compilation of guidelines	1
Document was a fact sheet	1
Total	129

4.3.3 National Health Priority Areas covered in the 74 guidelines assessed

The number of guidelines in each National Health Priority Area is shown in Table 7. The most common National Health Priority Areas covered by the guidelines were cancer control (26 guidelines), mental health (15 guidelines) and cardiovascular health (13 guidelines).

Table 7: National Health Priority Area for 74 guidelines in the study (not mutually exclusive)

National Health Priority area	Number of guidelines
Cancer control	26
Mental health	15
Cardiovascular health	13
Diabetes mellitus	8
Injury prevention and control	6
Arthritis and musculoskeletal conditions	5
Asthma	5
Obesity	1
Dementia	0

There were five guidelines that covered two National Health Priority Areas, for example, *Psychosocial management of adolescents and young adults with cancer: guidance for health professionals* (guideline number 56) is in the National Health Priority Areas of mental health and cancer. The year of publication of the 74 guidelines is listed in Table 8. Fifteen guidelines (20.3%) were approved by the NHMRC.

Table 8: Year of publication for 74 guidelines in the study

Year of publication of guideline	**Number of guidelines (n, %)**
2010	10 (14)
2011	21 (28)
2012	13 (18)
2013	19 (26)
2014	11 (15)
Total	74 (100)

The types of organisation or individuals involved in the development of the 74 guidelines in the study are shown in Table 9. Most commonly (29 guidelines) the primary guideline development group was a multidisciplinary non-government organisation. Examples of these included the National Heart Foundation, the Cancer Council, Kidney Health Australia and research institutes. The NHMRC was the guideline developer for four guidelines. No guidelines on the portal were developed by Aboriginal Community Controlled Organisations at a national, state or local level. Membership-based consumer organisations were responsible for developing only one clinical practice guideline. However, it is relevant that many of the non-government organisations such as the Cancer Council, the Asthma Foundation and the National Heart Foundation also have a strong consumer base but are not membership-based consumer organisations.

Table 9: Primary guideline developers for 74 clinical practice guidelines

Primary guideline developers	**Number (%)**
Multidisciplinary non-government organisation	29 (39.2)
Federal government body (not including NHMRC)	10 (13.5)
Specialty society	7 (9.5)
State health department	6 (8.1)
University	5 (6.8)
National Health and Medical Research Council	4 (5.4)
Medical college	4 (5.4)
Networks of clinicians	3 (4.0)
Condition-specific group that is not a NGO	2 (2.7)
Health professional organisation (non-medical)	2 (2.7)
Consumer organisation	1 (1.4)
Individual clinician	1 (1.4)
Total	74

Thirteen guidelines had a second guideline development group named as a guideline developer. Of these 13, the secondary guideline developers were non-government organisation (7), specialty society (2), medical college (2), Federal government department (1) and other professional organisation (1).

4.3.4 Intended audience

Most guidelines (69, 93.2%) were intended for an Australian or Australian/New Zealand audience, with the remainder (5, 6.8%), intended for a state-based audience. There were no guidelines intended for international and Australian audiences.

For 39 (52.7%) of the guidelines, the target audience was specifically stated and is shown in Table 10, noting that the categories are not mutually exclusive. General practitioners were the target audience for 31 guidelines, medical specialists for 28 guidelines, other medical practitioners for 20 guidelines and nurses for 23 guidelines. Aboriginal health workers were specifically stated as a target audience for 11 guidelines.

Table 10: Target audience in 39 guidelines where the target audience was specified (categories not mutually exclusive)

Health professional group	**Number specified as a target audience**
General practitioners	31
Medical specialists	28
Nurses	23
Aboriginal health care workers	11
Psychologists	11
Mental health care workers	8
Physiotherapists	7
Dieticians	5
Occupational therapists	5
Pharmacists	4
Podiatrists	3
Social workers	3
Radiographers	2
Dentists	2
Drug and alcohol workers	1

4.3.5 Stated use of other guideline development frameworks

In most of the guidelines (55, 74.3%) reviewed, a known framework or approach for developing the guideline was not specified. Of the 19 guidelines where a framework or approach was specified, 12 (16.2%) made specific reference to NHMRC standards for clinical practice guidelines (NHMRC 1999b; NHMRC 2011). Four guidelines referred to the use of the AGREE instrument (National Collaborating Centre for Methods and Tools 2011). These categories were not mutually exclusive because some guidelines mentioned more than one framework/approach. Other international frameworks for guideline development, such as those from the National Institute of Clinical Excellence or World Health Organization (Eccles et al. 2012;

World Health Organization 2012) were not used because they were only available from 2012 and would only have been relevant to guidelines in the study sample published after this time. No guideline mentioned or used the NHMRC guidelines for incorporating socioeconomic evidence into clinical practice guidelines (NHMRC 1999a). No guideline made reference to any other guidelines or frameworks which specifically related to health equity such as the previously cited PROGRESS (Hill et al. 2014) or PROGRESS plus (O'Neill et al. 2014) lens for systematic reviews or the INCLEN equity in guidelines tool (Dans et al. 2007).

4.3.6 Assessment of the quality of guidelines using the iCAHE checklist

As described in Chapters 1 and 3, the previously developed and validated iCAHE rapid checklist for assessing methodological quality of guidelines (Grimmer et al. 2014) was used to assess and quantify the quality of the guidelines in the study sample with the purpose of exploring associations between methodological quality of guidelines and the variables collected in the AGEL Version 3. The iCAHE checklist comprises 14 features of guidelines that contribute to overall methodological quality. The maximum score is 14 for a high-quality guideline and the minimum score is 4.

When the iCAHE Guideline quality checklist was applied to assess the overall quality of guidelines, there was wide variability in their quality. The median score in the sample was 11, and the range was 4–14. Twenty-four CPGs had an iCAHE score of 13 or 14, indicative of a guideline with high methodological quality. Thirty-one guidelines (41.5%) had a score of under 10. iCAHE scores for the 74 guidelines are shown in Figure 2, demonstrating this. The results of the assessment of each of the 14 dimensions of quality that contributed to quality assessment are listed in Table 11.

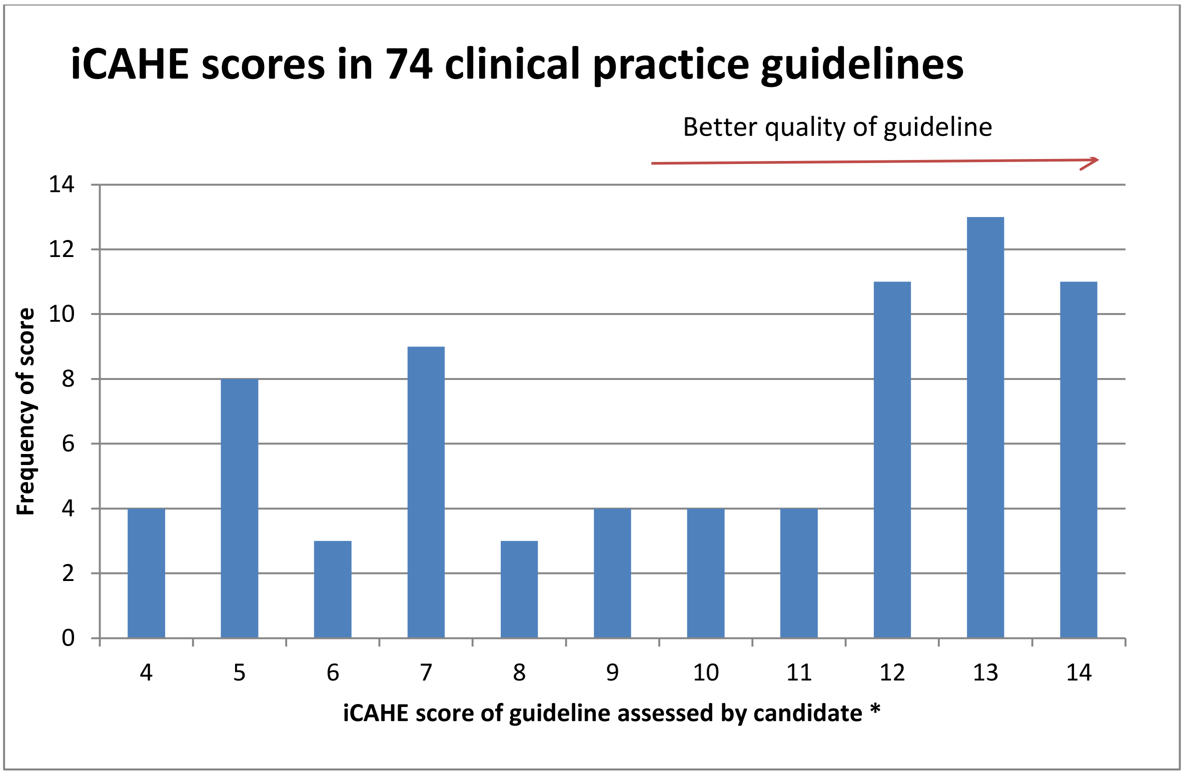

Figure 2: Overall quality of 74 guidelines by iCAHE score (Grimmer, 2014)

Table 11: Application of the iCAHE guideline (Grimmer, 2014) quality checklist, frequency of response to 14 questions about each of 74 guidelines

Questions about guideline/dimension of quality	**“Yes”**	**“No”**
1. Is the guideline available in full text?	74	0
2. Does the guideline provide a complete reference list?	68	6
3. Does the guideline provide a summary of its recommendations?	55	19
4. Is there a date of completion available?	67	7
5. Does the guideline provide an anticipated review date?	13	61
6. Does the guideline provide dates for when literature was included?	50	24
7. Does the guideline provide an outline of the strategy they used to find underlying evidence?	46	28
8. Does the guideline use a hierarchy to rank the quality of the underlying evidence?	45	29
9. Does the guideline appraise the quality of the evidence which underpins its recommendations?	46	28
10. Does the guideline link the hierarchy and quality of underlying evidence to each recommendation?	39	35
11. Are the developers of the guideline clearly stated?	74	0
12. Does the qualifications and expertise of the guideline developer(s) link with the purpose of the guideline and its end users?	69	5
13. Are the purpose and target users of the guideline stated?	39	35
14. Is the guideline readable and easy to navigate?	71	3

Table 12: List of 74 guidelines with the iCAHE scores using the iCAHE guideline quality checklist

Score /14	Guideline topic
14	• Recommendations for the identification and management of fear of cancer recurrence in adult cancer survivors • Clinical practice guidelines for the management of rotator cuff injury in the workplace • Clinical practice guideline for the management of borderline personality disorder • Depression in adolescents and young adults • Evidence-based practice guidelines for the dietetic management of adults with pressure injuries • Clinical practice guidelines for the management of overweight and obesity in adults, adolescents and children in Australia • Australian guidelines for the treatment of acute stress disorder and posttraumatic stress disorder • Guidelines for screening, assessment and treatment in problem gambling • Guidelines for the management of absolute cardiovascular disease risk • Australian and New Zealand guideline for hip fracture care: improving outcomes in hip fracture management of adults • Clinical practice guidelines. Depression and related disorders, anxiety, bipolar disorder and puerperal psychosis in the perinatal period
13	• Recommendations for the identification and management of CNS metastases in women with secondary breast cancer • General practice management of type 2 diabetes • Cancer pain management in adults • Guidelines for the diagnosis and treatment of malignant mesothelioma • Clinical practice guidelines for the management of adult onset sarcoma • Clinical practice guidelines for surveillance colonoscopy • National evidence based clinical care guidelines for type 1 diabetes in children, adolescents and adults • Clinical guideline for the prevention and treatment of osteoporosis in postmenopausal women and older men • Consensus-based clinical practice guideline for the management of volatile substance use in Australia • Clinical practice guidelines for the psychosocial care and bereavement support of family caregivers of palliative care patients • Royal Australian and New Zealand College of Psychiatrists clinical practice guideline for the treatment of eating disorders • National guidelines for medication-assisted treatment of opioid dependence
12	• First-line chemotherapy for the treatment of women with epithelial ovarian cancer. Recommendations for the use of first-line chemotherapy for the treatment of women with epithelial cancer • Recommendations for the management of early breast cancer in women with an identified BRCA1 or BRCA2 gene mutation or at high risk of a gene mutation • Clinical practice guidelines for the management of locally advanced and metastatic prostate cancer • Evidence-based guidelines for the management of hip fractures in older

persons: an update
- Guidelines for the prevention and management of chronic heart failure in Australia
- Prevention and management of chronic kidney disease in type 2 diabetes (includes separate paper: Cost-effectiveness and socioeconomic implications of prevention and management of chronic kidney disease)
- Working with the suicidal person: clinical practice guidelines for emergency departments and mental health services
- Clinical practice guidelines for the treatment and management of endometrial cancer
- Evidence based practice guidelines for the nutritional management of adult patients with head and neck cancer
- Psychosocial management of AYAs diagnosed with cancer: guidance for health professionals
- Recommendations for follow-up of women with early breast cancer
- Clinical guidance for responding to suffering in adults with cancer

11
- Abuse and violence. Working with our patients in general practice (4th edition).
- Australian and New Zealand clinical practice guideline for prevention and management of venous leg ulcers
- Recommendations for use of chemotherapy for the treatment of advanced breast cancer
- Fertility preservation for AYAs diagnosed with cancer: guidance for health professionals

10
- Cardiovascular disease: revascularisation
- Type 2 diabetes in young Indigenous Australians in rural and remote areas: diagnosis, screening, management and prevention
- Recommendations for the management of women at high risk of ovarian cancer
- Treatment of osteoporosis in Australian residential aged care facilities: consensus recommendations for fracture prevention

9
- Asthma and wheezing in the first years of life: an information paper for health professionals
- The Australian guideline for prevention, diagnosis and management of acute rheumatic fever and rheumatic heart disease (2nd edition)
- Guide to management of hypertension
- Recommendations for staging and managing the axilla in early (operable) breast cancer

8
- South Australian head and neck cancer pathway
- Clinical practice points on the diagnosis, assessment and management
- Follow up of women with epithelial ovarian cancer

7
- Clinical guiding principles for sick day management of adults with type 1 and type 2 diabetes
- Asthma and the over 65s. An information paper for health professionals
- Building healthy bones throughout life: an evidence-informed strategy to prevent osteoporosis in Australia
- South Australian hepatocellular cancer care pathway
- Australian Diabetes Foot Network: management of diabetes-related foot

	ulceration, a clinical update • Managing allergic rhinitis in people with asthma • Alcohol and other drug withdrawal: practice guidelines • Reducing risk in heart disease. An expert guide to clinical practice for secondary prevention of coronary artery disease • Clinical practice guideline: multiple myeloma
6	• Asthma and healthy living. An information paper for health professionals • South Australian gynaecological cancer care pathway: optimising outcomes for women with gynaecological cancer • The South Australian gastroenteropancreatic neuroendocrine tumours pathway
5	• Diabetes management in general practice • Clinical guidelines for the physical care of mental health consumers • Peri-operative diabetes management guidelines • Guidelines for the diagnosis and management of Brugada syndrome • Practice guidelines for treatment of complex trauma and trauma informed care and service delivery • Guidelines for the diagnosis and management of catecholaminergic polymorphic ventricular tachycardia • Guidelines for the diagnosis and management of familial long QT syndrome • South Australian lung cancer pathway
4	• Cardiovascular effects of blood pressure lowering in patients with chronic kidney disease • Guidelines for the diagnosis and management of familial dilated cardiomyopathy • Guidelines for the diagnosis and management of hypertrophic cardiomyopathy • Asthma and allergy: an information paper for health professionals

As mentioned in Chapter 1, another key factor in relation to the quality and acceptability of guidelines is the declaration of a conflict of interest (Ghersi and Anderson 2015). Only 35 (47.3%) of the guidelines reviewed had a declaration of conflict of interest.

4.3.7 References to equity, inequality or socioeconomic disadvantage in 74 clinical practice guidelines

Of the 74 guidelines in the study, fewer than one-third (n=23, 31.1%) had specific references to equity, inequality or socioeconomic disadvantage. Of these, only one guideline referred to “health equity” as a concept, one guideline referred to “inequity” and the remaining 21 guidelines focused on or mentioned socioeconomic determinants or socioeconomic disadvantage. No guideline referred to fairness or human rights (Table 13). Appraisal of the guidelines using the INCLEN equity in guidelines tool dimensions (Table 15, p. 98) identified that there was a discussion of the burden of disease in disadvantaged populations in 23 guidelines. That these scores were the same using two different questions about the same construct in two different ways demonstrates concurrent validity in the application of the AGEL Version 3 to these guidelines for the determination of the visibility of equity and socioeconomic determinants. Concurrent validity refers to the extent to which the measurement of a construct, in this case measurement of the consideration of socioeconomic determinants by the relevant collection of a variable in the AGEL, is the same as the measurement of a construct determined by a different question, in this case a field from the INCLEN appraisal tool assessing equity in clinical practice guidelines.

Table 13: Frequency of the evidence of the visibility of equity and socioeconomic determinants in 74 clinical practice guidelines

Evidence	**Yes**	**No**
Specific references to socioeconomic disadvantage	23	51
Specific references to equity/inequality	2	73
Specific references to human rights or fairness	0	74
Evidence on social gradient or socioeconomic position has informed the guideline recommendations	19	55
Gaps in relation to data or research on social gradient has been identified in the guidelines	12	62
Guidelines presents an analysis of the clinical issue related to socioeconomic position (NHMRC recommendation)	19	55
Mention of PROGRESS lens for systematic reviews being taken into account	0	74
Consumer/client representation documented in the guideline development process	43	31
Specific population groups/special populations are given specific attention	50	24
NHMRC guidance for incorporating evidence about socioeconomic position in clinical practice guidelines referenced	0	74

The review of guidelines using the AGEL identified that one guideline considered equity and socioeconomic determinants more extensively than others. This was the Cancer Council Australia's *Clinical practice guidelines for surveillance colonoscopy in adenoma follow-up following curative resection of colorectal cancer in inflammatory bowel disease* (Cancer Council Australia Colonoscopy Surveillance Working Party 2011). Specifically, this guideline mentioned equity and had a section of five pages where there was discussion of the impact of socioeconomic factors on patients and on treatment outcomes. This clinical practice guideline specifically addressed Aboriginal and Torres Strait Islander populations and flagged areas for further research in relation to the effect of socioeconomic determinants on recommendations in the guidelines. There was also consumer involvement in this guideline. The guideline was also of good overall methodological quality, as assessed using the iCAHE instrument, with a score of 13 (Grimmer et al. 2014).

In the 23 guidelines where discussion of equity or socioeconomic determinants/disadvantage was evident, this occurred in the literature review or background section. For 19 of these guidelines, reference to equity or socioeconomic position was also made in the recommendations or guidance, and in 12 guidelines reference was made in sections that identified gaps or made references for further research.

There was clear evidence that social gradient or socioeconomic position had informed the guidance recommendations in only one-quarter of the guidelines (n=19, 25.7%) (Table 13). In the 12 guidelines where gaps were identified in relation to data or research on social gradient in the guidelines, this was specified in the guideline literature review (n=12), the guidance section/recommendations (n=8) and/or a specific section relating to gaps or further research (n=8). These categories were not mutually exclusive.

The guidelines that were significantly more likely to consider equity or socioeconomic determinants were clinical practice guidelines which used the standards for the development of guidelines (NHMRC 1999a, 1999b) as a framework (χ^2=4.9, df=1. p=.03). Guidelines approved by the NHMRC (χ^2= 4.29, df=1, p=.038) and those where there was consumer or client representation in guidelines development (χ^2= 4.45, df=1, p=.034) were also significantly more likely to consider equity or socioeconomic determinants, as were mental health guidelines (χ^2= 4.29, df=1, p=.038).

Analysis of variance showed that those guidelines with better methodological quality, as assessed using the iCAHE instrument, were not significantly more likely to consider equity and socioeconomic determinants ($F_{1,72}$=2.81, p=.098).

4.3.8 Rationale for inclusion of socioeconomic considerations in guidelines

In the 23 guidelines where there was mention of social determinants or socioeconomic considerations (even if equity was not specifically mentioned), the rationale for inclusion was stated in most instances. The most frequent reason was that there was evidence of the impact of socioeconomic status on the health issue (n=21) being considered. Other reasons given for including these considerations were consistency with government policy (n=3), addressing socioeconomic determinants was a stated priority for the guideline development organisation (n=3) or a requirement of the stakeholder (n=1). These categories were not mutually exclusive. In no guideline was human rights or fairness justifications mentioned and no guidelines justified inclusion of these concepts as a result of the NHMRC (1999a) document, *Using socioeconomic evidence in clinical practice guidelines* or the *WHO handbook for guideline development*, equity chapter (World Health Organization 2012).

The PROGRESS lens became available late in 2013 and allows for an analysis of systematic reviews by a lens of stratifiers. It was only relevant for those guidelines published in late 2013 and 2014. There was no mention of this lens in any clinical practice guidelines.

Consumer representation was described in the guideline development process in over half of the guidelines (n=43, 58.1%). Consumer representation in the guideline development process was more likely to be reported in guidelines that used the NHMRC standards for guidelines as a framework than those that did not (χ^2=10.1, df=1, p=.001). As discussed in Chapter 1, these standards encourage stakeholder involvement in guidelines development, but use of them was not mandatory for guidelines other than for those where NHMRC approval was required. Consumer representation in guideline development was also significantly associated with higher iCAHE scores when analysed using a one-way ANOVA ($F_{1,72}$=40.45, p=.00).

4.3.9 Specific attention given to special populations

Just over two-thirds of guidelines (n=50, 67.5%) gave specific attention to special populations, as shown in Table 14. Aboriginal and Torres Strait Islander communities or populations were given specific attention in fewer than half of the guidelines (n=33, 44.6%), but they were more likely to be given specific attention if there was consumer representation in the guideline (χ^2= 7.52, df=1, p=.001) or if the guidelines used the NHMRC standards for development of guidelines (χ^2= 9.41, df=1, p=.002), which recommend consideration of special populations (NHMRC 1999a). Analysis of variance identified a significant association between guidelines which considered Aboriginal and Torres Strait Islander populations and those with better methodological quality as assessed by the ICAHE score ($F_{1,72}$=7.49, p=008). This means that guidelines with better methodological quality were more likely to have considered Aboriginal and Torres Strait Islander populations. There was also a significant association between guidelines which considered “people from low socioeconomic backgrounds” and better methodological quality ($F_{1,72}$=6.00, p=.017). Clinical practice guidelines where the NHMRC *Standards for clinical practice guidelines* were used as a framework were more likely to give specific attention to people from low SES groups (χ^2= 7.9, df=1, p=.005).

Table 14: Number of guidelines in which special populations/groups were given specific attention in 50 guidelines (categories not mutually exclusive)

Group	**Number of guidelines (% of 74 guidelines)**
Aboriginal and Torres Strait Islander	33 (44.6)
People from culturally and linguistically diverse backgrounds	21 (28.3)
People from low-socioeconomic backgrounds	19 (25.7)
People with mental health issues	19 (25.7)
Children and young people	19 (25.7)
Women	17 (23.0)
Older people	15 (20.2)
People with disabilities	2 (2.7)

4.3.10 Consistency of 74 guidelines with INCLEN equity in guidelines tool

As was seen in the results section of Chapter 3, pilot testing and previous work had shown that several of the questions derived from the INCLEN equity in guidelines tool (Dans et al. 2007) required a subjective assessment of whether the guideline topic was a priority problem for a disadvantaged population. These results are therefore presented for completeness of reporting of the dataset. For 41 of the guidelines and based on the use of the questions from the INCLEN tool, there was no evidence or it could not be concluded that “the recommendations in the guidelines might address a priority problem for disadvantaged populations”. This was because the question of priority problems for disadvantaged populations was not specifically stated in the guideline and there was no other way of inferring this from the guideline. Specific attention was given to “minimising barriers in implementation in the guidelines in disadvantaged populations” in 24 guidelines (32.4%). However, there was no evidence of “plans or proposed strategies” to address this in any of the 74 guidelines or for assessing the impact or outcome of the guidelines in disadvantaged populations. There was a reference to the effects of interventions being considered (valued) differently by disadvantaged populations in four (5.4%) guidelines, although the term “values” was never used. For three of the INCLEN criteria, it was not possible to decide how to rate the guideline according to that criterion (Table 15). This demonstrated the overall difficulty in using these criteria and confirmed similar feedback of poor usability and reliability of these fields within the online AGEL Version 3 from pilot testing, as discussed in Chapter 3.

Table 15: Appraisal of criteria relating to equity in 74 clinical practice guidelines using the INCLEN equity in guidelines tool

Appraisal criterion	Yes (%)	No (%)	Unsure (%)
Do the recommendations in the guidelines address a priority problem in disadvantaged populations?	33 (44.6)	23 (31.1)	18 (24.3)
Is there a reason for the guideline developers to anticipate different effects of interventions in disadvantaged and privileged populations?	32 (43.2)	15 (29.3)	27 (36.4)
Are the effects of the intervention valued differently by disadvantaged compared to privileged populations?	4 (5.4)	11 (14.9)	61 (82.4)
Is specific attention given to minimising barriers to implementation in disadvantaged populations?	23 (31.1)	51 (68.9)	0
Do plans for assessing the impact of the recommendations include assessing the impact/outcome in disadvantaged populations?	0	74 (100)	0

4.3.11 Visibility of equity and socioeconomic determinants using checklist items derived from the WHO handbook for guideline development

The checklist items derived from the *WHO handbook for guideline development* (World Health Organization 2014) were consistent with the overall findings of other parts of the AGEL about the visibility of equity in the 74 clinical practice guidelines. The frequencies with which considerations for integrating equity, human rights and gender were included in 74 guidelines, as proposed by the World Health Organization, are shown in Table 16. There were 23 guidelines (31%) that documented the need to take into account the potential for differences in uptake and benefits as a function of social position. However, there was evidence in only 14 (18.9%) guidelines that the systematic reviews used to inform guideline development explicitly described the potential effect of interventions, not only on the population overall but also on the social gradient or specific populations. This is surprising given my assessment from a review of the list of guideline development group members that over half (40, 54%) of the guidelines developers included individuals who would have an understanding of equity issues. Where evidence on equity was sparse, conditional recommendations were made outlining key gaps in knowledge and an agenda for future research in only 9 (12.1%) guidelines.

Table 16: Assessment of 74 guidelines using the World Health Organization Handbook specifications for integrating equity, human rights and gender into guidelines

World Health Organization criteria for integrating equity into guidelines	**Yes (%)**	**No (%)**
Does the guideline convey *clear* messages with respect to equity, human rights, gender or social determinants (intent)?	9 (12.2)	65 (87.8)
Is there evidence that the guideline development group includes individuals who would have an understanding of equity issues?	40 (54.1)	34 (45.9)
Is there a declaration of conflict of interest?	35 (47.3)	39 (52.7)
Does the guideline take into account the potential for differences in uptake and benefits as a function of social position?	23 (31.1)	51 (68.9)
Is there evidence that the systematic reviews used to inform guideline development explicitly describe the potential effect of interventions not only on the population as a whole but across the social gradient?	14 (18.9)	60 (81.1)
Where information on equity is sparse in evidence, are conditional recommendations made, outlining key gaps in knowledge and an agenda for future research?	9 (12.2)	65 (87.8)

4.4 Visibility of equity and socioeconomic determinants by characteristics of the guideline or guidelines topic

4.4.1 Analysis of the 15 National Health and Medical Research Council-approved guidelines for the visibility of equity

Of the 15 guidelines which were approved by the NHMRC, seven (46.7%) were produced by multidisciplinary non-government organisations, four (26.7%) by the NHMRC, and the others by medical colleges (n=1) or universities (n=2). Only eight guidelines made specific reference to either edition of the NHMRC guidelines for the development of clinical practice guidelines as a framework for developing the guidelines. The national health priority areas covered in the NHMRC-approved guidelines are shown in Table 17.

Table 17: National Health Priority Areas of 15 guidelines approved by the NHMRC (categories not mutually exclusive)

National Health Priority Area	**Number of guidelines**
Mental health	7
Arthritis and musculoskeletal conditions	2
Injury prevention and control	2
Cancer control	2
Cardiovascular health	2
Diabetes mellitus	1
Obesity	1

Aboriginal and Torres Strait Islander populations were given specific consideration in 12 (80%) of the 15 NHMRC-approved guidelines, while people from low socioeconomic groups were given specific consideration in fewer than half (7, 46.7%) of NHMRC-approved guidelines, as shown in Table 18. One guideline approved by the NHMRC did not give specific attention to any special populations or disadvantaged groups.

Table 18: Special populations/disadvantaged groups given specific consideration in 15 guidelines approved by the NHMRC (categories not mutually exclusive)

Special population/disadvantaged group	**Number of guidelines**
Aboriginal and Torres Strait Islander	12 (80%)
People from culturally and linguistically diverse backgrounds	9 (60%)
Persons with mental health issues	8 (53.3%)
Children and young people	8 (53.3%)
People from low socioeconomic groups	7 (46.6%)
Women	5 (33.3%)
Older people	4 (26.7%)
People with disabilities	1 (6.7%)

There was specific reference to socioeconomic disadvantage, or an analysis of the clinical issue related to socioeconomic position, in eight of the 15 guidelines and reference to equity in only one guideline. Evidence on social gradient or socioeconomic position was found to inform guidance recommendations in just over half of the guidelines approved by the NHMRC (n=8, 53.3%). Similarly, these eight guidelines were the only ones to give specific attention to minimising barriers to implementation in disadvantaged populations or providing strategies to overcome these barriers. Gaps in data or research on social gradient and equity were identified in fewer than half of the guidelines (n=7, 46.7%) and conditional recommendations, outlining gaps in knowledge and an agenda for future research were made in 40% of guidelines (n=6). Despite these findings, by using the AGEL it was possible to identify that all 15 guidelines had evidence that the guideline development group included individuals who would have an understanding of equity issues. The overall quality of guidelines was good, according to ratings using the iCAHE instrument (Grimmer et al. 2014), with a mean score of 13.1 out of 14. However, there was variability in the score, with the range from 8 to 14.

Guidelines approved by the NHMRC were significantly more likely to contain specific reference to equity or socioeconomic determinants than other guidelines in this sample (χ^2=29.07, df=1, p=000); were more likely to have consumer representation in the guidelines development process (χ^2=7.52, df=1, p=.006) and were more likely to consider Aboriginal and Torres Strait Islander populations (χ^2 = 9.42, df=1, p=002)

4.4.2 Analysis of the 26 cancer guidelines for visibility of equity and socioeconomic determinants

Cancer was the most common National Health Priority Area covered in this study, with 26 of the guidelines (35.1%) being related to it. The type of primary guideline development group for these is shown in Table 19. Of the 26 cancer guidelines, 22 were developed by either multidisciplinary non-government organisations or government agencies.

Table 19: Type of primary guideline development group for 26 cancer guidelines

Type of guideline development group	**Number of guidelines**
Federal government body (not NHMRC)	9
Multidisciplinary non-government organisation	8
State health department	5
Specialty society	2
Condition-specific group	1
University	1
Total	26

Only two (7.7%) of the guidelines were approved by the NHMRC and only four of the 26 (15.3%) referred to the NHMRC standards for the development of guidelines. The overall quality of the guidelines was variable, with the mean iCAHE score being 10.65 and the range from 5 to 14.

Over three-quarters of the guidelines (n=20, 76.9%) described consumer representation in the guideline development process. Only six of the guidelines specifically referred to equity or socioeconomic determinants while nine of the 26 cancer guidelines gave specific attention to Aboriginal and Torres Strait Islanders. Six guidelines referred to culturally and linguistically diverse communities (Table 20).

Table 20: Special populations/disadvantaged groups given specific consideration in 26 cancer guidelines (categories not mutually exclusive)

Special population/disadvantaged group considered	Number of guidelines
Aboriginal and Torres Strait Islander	9 (34.6%)
People from culturally and linguistically diverse backgrounds	6 (23.0%)
People from low socioeconomic groups	6 (7.6%)
Women	4 (15.4%)
Older people	3 (11.5%)
Children and young people	2 (7.7%)
People with mental health issues	2 (7.7%)
People with disabilities	1 (3.8%)

Cancer guidelines were more likely to include consumer representation in their development than other guidelines in this sample (χ^2=5.75, df=1, p=.016). Despite this, only six (23.1%) guidelines referred to socioeconomic status or socioeconomic position, with only four of those (15.4% of total) presenting an analysis of the clinical issue related to socioeconomic position and only four (15.4%) stating identified gaps in data or research on social gradient and equity. Conditional recommendations outlining key gaps in knowledge or an agenda for future research were identified in only two (7.7%) of the cancer guidelines.

4.4.3 Analysis of the 15 mental health guidelines for visibility of equity

Mental health guidelines ranked as the second most common National Health Priority Area covered in guidelines studied, with 15 of the guidelines (20.2%) being related to mental health or dependence. This group of guidelines had a high overall quality with a median iCAHE score of 13, indicating that more than half of the guidelines were of very high quality, although the range of 5–14 showed there was variability. Nearly half the mental health guidelines (7/15) had specific references to socioeconomic disadvantage or status and in these seven guidelines there was evidence that socioeconomic position or social gradient had informed guideline recommendations. Gaps in data about socioeconomic evidence or socioeconomic position were identified in four of the 15 guidelines and conditional recommendations were made in three (20%) of them. The type of primary guideline development group for 15 mental health guidelines is shown in Table 21. Three guidelines were developed by the NHMRC.

Table 21: Type of primary guideline development group for 15 mental health guidelines

Type of guideline development group	Number of guidelines
University	3
National Health and Medical Research Council	3
Multidisciplinary non-government organisation	3
Medical college	2
Consumer organisation	1
Federal government body (not NHMRC)	1
State health department	1
Specialty society	1

Aboriginal and Torres Strait Islander communities were mentioned in nearly three-quarters (73.3%) of the mental health guidelines and nearly all guidelines (86.7%) specifically considered children and young people (Table 22). The inclusion of special populations in mental health guidelines was higher than in guidelines in other National Health Priority Areas.

Table 22: Special populations/disadvantaged groups given specific consideration in 15 mental health guidelines (categories not mutually exclusive)

Special population/disadvantaged group considered	Number of guidelines
Children and young people	13 (86.7%)
Aboriginal and Torres Strait Islander	11 (73.3%)
People from culturally and linguistically diverse backgrounds	9 (60.0%)
Women	8 (53.3%)
People from low socioeconomic groups	7 (46.7%)
Older people	3 (20.0%)
People with disabilities	2(13.3%)

4.4.4 Characteristics or predictors of guidelines in which equity or socioeconomic determinants are highly visible or where special attention is given to Aboriginal and Torres Strait Islander populations.

Of the 23 guidelines where there were specific references to socioeconomic disadvantage, equity or inequity, a large proportion (n=17, 73.9%) described consumer or client representation in the guideline development process. Eight of the 23 guidelines were NHMRC-approved. Seven of the 23 guidelines referred to the NHMRC standards for the development of guidelines. The years of publication of these guidelines was 2010 (3), 2011 (6), 2012 (4), 2013 (6), 2014 (4).

The National Health Priority Areas covered by the guidelines were: cancer control (6), cardiovascular health (4), injury prevention and control (2), mental health (8), diabetes mellitus (3), arthritis and musculoskeletal conditions (1), and obesity (1). The 23 guidelines that mentioned either equity or socioeconomic determinants were significantly more likely also to give specific attention to Aboriginal and Torres Strait Islander communities (χ^2= 29.07, df=1, p=.000), with 21 of these guidelines considering Aboriginal and Torres Strait Islander populations. Of the 23 guidelines where socioeconomic disadvantage, equity or inequity was mentioned, 15 gave specific attention to people from culturally and linguistically diverse backgrounds, and guidelines which mentioned equity or socioeconomic determinants were also significantly more likely to consider culturally and linguistically diverse populations (χ^2=21, df=1, p=.002). Of the 23 guidelines mentioning equity or socioeconomic determinants, the majority (n=18, 78.3%) used evidence on socioeconomic position or social gradient to inform the guidance recommendations, but only half identified gaps in relation to data or research on social gradient and equity (n=12, 52.2%).

Among these 23 guidelines, there was variable overall methodological quality as measured by the iCAHE score, with a range of 5–14 and a median score of 12. However, analysis of variance did not show a statistically significant association between methodological quality of guidelines and specific reference to equity or socioeconomic determinants of guidelines ($F_{1,72}$ =82.98, p=0.098).

4.4.5 Characteristics of guidelines that specifically considered Aboriginal and Torres Strait Islander populations

Of the 33 guidelines that specifically mentioned Aboriginal and Torres Strait Islander populations, nine were in cancer control, four were in cardiovascular health, four were in injury prevention and control, eleven were in mental health, five were in diabetes mellitus, two in arthritis and musculoskeletal conditions, and one in obesity. None of the asthma guidelines mentioned Aboriginal and Torres Strait Islander populations. Of the 33 guidelines, about one-third (n=12, 36.4%) used a guideline development framework, most often the NHMRC guidelines (n=8), although the AGREE instrument (n=3) and the ADAPTE process (n=1) were also used. Of the 33 guidelines that considered Aboriginal and Torres Strait Islander populations, 21 (63.6%) made specific reference to socioeconomic disadvantage. Gaps in relation to research on social gradient were identified in just over one-third of these guidelines (n=12, 36.4%). Nine (27.3%) made conditional recommendations outlining key gaps and an agenda for future research. Consumer representation in the guideline development process was described in 25 (75.8%) of these guidelines, although this was not necessarily Aboriginal and Torres Strait Islander consumer representation. The overall quality of the guidelines where Aboriginal and Torres Strait Islander populations were mentioned was satisfactory, with a median ICAHE score of 12 although quality was variable with a range of 5–14.

This concludes the results of examining 74 guidelines with the AGEL Version 3. A discussion of the findings of the research, its limitations and the dissemination plan is presented in Chapter 5**.**

Chapter 5: Discussion and research dissemination plan

In this research, an instrument to assess the visibility of equity and socioeconomic determinants in Australian clinical practice guidelines in National Health Priority areas was developed and applied to 74 guidelines on the NHMRC Clinical Practice Guidelines Portal. In this chapter, the findings of the study will be discussed within a public health policy context. The implications of findings for public health policy and future research will be considered. Limitations of the research methods used in the research will be outlined. Consistent with the requirements of the Doctorate of Public Health dissertation, the chapter also includes a dissemination plan for the research. As required, a brief summary document for the “target constituency”, in this case, the NHMRC Synthesis and Translation of Research Evidence Advisory Group, is included at Appendix 6.

5.1 Guidelines, equity and socioeconomic determinants

As explored in the introduction (Chapter 1), clinical practice guidelines have the potential to provide guidance to practitioners to assist them in considering equity in clinical practice (Aldrich et al. 2003; Dans et al. 2007; World Health Organization 2012). Guidelines may lessen health inequity by including recommendations that redress the impact of socioeconomic disadvantage in healthcare (Aldrich et al. 2003; Dans et al. 2007; National Institute of Clinical Excellence 2012; World Health Organization 2012). They may also create inequities by ignoring socioeconomic impacts on health outcomes, by not specifically considering the needs of special populations or by not seeking and using socioeconomic evidence (Aldrich et al. 2003; Dans et al. 2007; Mizen et al. 2012). In public health terms, clinical practice guidelines for common health conditions such as cancer, heart disease or diabetes could broaden health inequalities within populations or sub-populations by not addressing barriers to health care access or by omitting recommendations that might address well-described differentials by socioeconomic position in risk factors or health outcomes for these conditions. Such omissions may result in further inequality in health status across the social gradient which, in turn, may potentially contribute to further socioeconomic disparities within populations. Public health policy currently sets the standards, parameters, resources and expectations of clinical practice guidelines development and approval processes. As will be discussed in this chapter, this research has practical implications for public health policy. This is because of the potential to influence the NHMRC standards for clinical practice guidelines ("guidelines for guidelines") development processes to improve the consideration of equity, socioeconomic determinants and disadvantaged populations in guideline development. As a result, this may then contribute to addressing equity or inequity in health care delivery in Australia.

The AGEL was developed with a Delphi panel, using a policy Delphi process (Gupta 2011) to assess the visibility of equity and socioeconomic determinants in Australian clinical practice guidelines in the nine National Health Priority Areas. The National Health Priority Areas are of public health relevance because they cover major common chronic diseases in Australia, such as cancer, diabetes, heart disease, musculoskeletal conditions and mental health disorders, and as such pose significant challenges for the public health system and public health policy (Australian Institute of Health and Welfare 2014, 2015). As detailed in Chapter 3, the equity lens, while being amenable to further development, had sound psychometric properties given its purpose for this study and it was used to assess the visibility of equity and socioeconomic determinants in guidelines. The lens also enabled identification of the circumstances where equity, socioeconomic determinants or special populations, such as Aboriginal and Torres Strait Islander communities, were considered and the factors associated with the inclusion of these in guidelines development.

This is the first published research that has included a comprehensive audit of systematically identified guidelines from a national database, while quantifying the inclusion of considerations about equity, socioeconomic determinants and disadvantaged populations in clinical practice guidelines. The NHMRC Clinical Practice Guidelines Portal had 558 guidelines published in the years 2010 to 2014 at the time of conducting this research. Guidelines from 2010 to 2014 were hand-searched to identify 203 guidelines in Australian National Health Priority Areas. After systematically excluding 129 guidelines because they did not fit the research inclusion criteria, 74 clinical practice guidelines were included in the study. A key finding in this study is that “equity” was only specifically mentioned in two of the 74 guidelines, with one guideline referring to “equity” and another referring to “inequity”. Consistent with the finding of low visibility of equity in Australian clinical practice guidelines, a lack of explicit and documented consideration of human rights or fairness in any guidelines was identified this research, despite this being nominated as a critical consideration in international standards for guidelines such as those of the World Health Organization (World Health Organization 2012) and the UK National Institute of Clinical Excellence (National Institute of Clinical Excellence 2012). While identification of the reasons for this was not an objective of this research, one possible reason might be that guideline developers do not consider the delivery of health care within a rights-based framework or value set but rather from a clinical perspective or other framework. Qualitative research with guideline developers, both individuals and guidelines development bodies, to explore the drivers and the underlying values underpinning guideline development would allow further elaboration of this. Intervention studies that evaluate the impact of discussions by guidelines development teams of values such as a focus on human rights would be useful in elucidating whether this results in a stronger commitment to inclusion of equity considerations in their clinical practice guidelines.

There are several possible interpretations of this lack of visibility of equity in the Australian clinical practice guidelines studied. Firstly, the absence of specific reference to equity suggests that equity has not been a strong consideration in the development of the Australian guidelines studied and therefore has not been mentioned. On one hand, had equity been considered carefully by guidelines development groups it is unlikely that principles of equity would have been expressed using different terminology, given that detailed national and international standards for guidelines development use these terms specifically. These standards provide extensive guidance on how equity considerations should be incorporated into guidelines (NHMRC 1999a; Aldrich et al. 2003, World Health Organization 2012). None of the guidelines referred to the NHMRC document *Using socioeconomic evidence in clinical practice guidelines* (NHMRC 1999). As discussed in Chapters 1 and 2, this document provides detailed guidance on how to include equity and socioeconomic determinants in guidelines.

On the other hand, it is also feasible that because other NHMRC standards for guideline development (NHMRC 1999b; NHMRC 2011) do not use this terminology, equity considerations may have been incorporated in a less purposeful or explicit manner and, consequently, this terminology was not used. In this circumstance, it is possible that considerations of equity were expressed in different ways, for example by including recommendations for special groups, or by discussing the impact of socioeconomic determinants on the condition being addressed in the clinical practice guidelines. However, mention of these occurred in only 23 of the guidelines out of the 74 reviewed, which is less than one-third of guidelines.

It is worth noting that no clinical practice guidelines published after 2012 made reference to World Health Organization standards for developing clinical practice guidelines, which place strong emphasis on equity in society, health equity and socioeconomic determinants (World Health Organization 2012). If these standards had been taken into account in guideline development, the guideline developers would have needed to demonstrate explicitly how equity and human rights were considered and how this influenced recommendations. This was not demonstrated in the clinical practice guidelines appraised in this study. The research was not intended to investigate how the guidelines groups which developed the guidelines determined what principles or values underpinned the guidelines development process. This could be important in understanding why equity considerations were mostly invisible in this set of guidelines. Such research might include a survey of guideline developers to explore values. The finding that equity was not an important factor in Australian clinical practice guidelines mirrors the findings of the limited number of smaller studies elsewhere which also found no, or minimal, evidence of equity in clinical practice guidelines (Dans et al. 2007; Mizen et al. 2012; Shi et al. 2014).

In this study, “socioeconomic determinants” or the impact of socioeconomic position in relation to the guideline topic were considered in only 23 guidelines. This is less than one-third of the guidelines studied. Only about one-quarter of guidelines (19) contained evidence that social gradient or socioeconomic position had informed any guidance recommendations. Use of the AGEL also identified that only 25% of guidelines in the study sample specifically considered “people from low socioeconomic backgrounds”. This is despite the existence since 1999 of a NHMRC document, easily accessible on its website, that provides a framework for inclusion of consideration of socioeconomic position in guidelines (NHMRC 1999a). This reference was not stated as being used in any of the 74 guidelines studied. Possible reasons for this might be that this document was not widely known or actively disseminated, or was not considered useful in guideline development. In light of this finding, further inquiry with key guideline development bodies as to why this document was not used or referred to may be warranted.

Similarly, there was also no reference to the PROGRESS framework for systematic reviews (O’Neill et al. 2014), an equity lens which provides a mechanism for considering key socioeconomic variables to be included in developing or interpreting reviews, although it is noted that this was not published until late 2013 and so was only available for guidelines in the study published in 2014. It has been previously argued, in the case of clinical practice guidelines, that the absence of consideration of socioeconomic position or socioeconomic determinants in guidelines reflects the poor quality of evidence available to develop guideline recommendations according to social stratifiers, such as socioeconomic status, sex, education or ethnicity/culture/language (Dans et al. 2007; Welch et al. 2010, 2015, 2016; Lorenc et al. 2013; O’Neill et al. 2014). However, only 12 guidelines identified gaps in the data about socioeconomic factors or stratifiers, in either the literature review of the guideline or in a specific section relating to future research.

It is encouraging to find in this study that guidelines which were formally approved by the NHMRC were significantly more likely to have considered equity or socioeconomic determinants than those which were not, suggesting that NHMRC approval potentially has an important place in enabling the inclusion of equity and socioeconomic determinants in clinical practice guidelines. Unfortunately, the most recent version of the NHMRC standards for guidelines (approved in 2016), which must be met before NHMRC approval is given for future guidelines, no longer includes the requirement for specific consideration of special groups, including Aboriginal and Torres Strait Islanders (NHMRC 2016). The potential impact of this on the visibility of equity and socioeconomic determinants could be monitored using the AGEL or a modification of it. A new NHMRC handbook is in development and will contain a chapter about equity. The results of research in this dissertation have significance for public health policy; the research has demonstrated quantitatively that earlier versions of this handbook had influence on the inclusion of considerations of equity and socioeconomic determinants and Aboriginal and Torres Strait Islander populations. Hence this research leads me to suggest that strengthening of the handbook with a chapter on equity is likely to have a further impact on public health policy related to equity in healthcare and to guidelines development overall.

As discussed in Chapter 1, the previous and current NHMRC standards for guidelines were primarily focused on addressing procedural, methodological and quality aspects of guidelines development (NHMRC 1999b, 2009, 2011, 2016). Quantitative analysis in this research has identified that inclusion of equity and socioeconomic determinants was not associated with better methodological quality of a guideline, as assessed by a rapid assessment tool for guideline methodological quality, the iCAHE instrument (Grimmer et al. 2014). However, methodological quality was significantly associated with consideration of the needs of Aboriginal and Torres Strait Islander populations in the guideline. Considerations of equity and socioeconomic determinants were also significantly more likely in guidelines where there was consumer or client representation in guidelines development. This finding is consistent with the well-described beneficial effects of consumer involvement in guideline development noted in other studies (Bastian 1996; Lanza and Ericsson 2000; Boivin et al. 2010; Nilsen et al. 2010; Díaz del Campo et al. 2011; Eccles et al. 2012; Tong et al. 2012). It is also consistent with Acosta's theoretical framework for inclusion of equity in guidelines, which proposed that target population involvement in guideline development was an important factor "in avoiding unjust differences" (Acosta et al. 2011). The present study also found that, of all guidelines in the various National Health Priority Areas, only mental health guidelines were significantly more likely to have visible consideration of socioeconomic determinants, with half of them (7 of 14) having specific references to socioeconomic determinants.

While the AGEL developed for this research was useful in identifying the consideration of equity and socioeconomic determinants in clinical practice guidelines or its absence, the tool was not designed to identify the degree of emphasis of these issues in the guidelines relative to other considerations, such as guideline quality. However, by appraising the guidelines in this study sample using this lens it was possible to identify guidelines that considered equity and socioeconomic determinants more thoroughly. Using the tool, one guideline relating to surveillance colonoscopy, for example, was identified as having references to equity, socioeconomic determinants, populations with specific needs and socioeconomic position (Cancer Council Australia Colonoscopy Surveillance Working Party 2011). Review of this guideline with the AGEL content analysis tool identified that there was strong consideration of equity, socioeconomic determinants and disadvantaged groups in the literature review and the recommendations, and there were specific recommendations relevant to Aboriginal and Torres Strait Islander patients. This was the only guideline that specifically mentioned equity as a concept. The guideline was also of high methodological quality, with an iCAHE score of 13 out of a maximum score of 14. Further research comprising a detailed content analysis of guidelines such as these would provide further insight into why and how this particular guideline was able to consider these matters so successfully. Evaluation of the impact of this guideline would also provide additional information about whether consideration of equity in guidelines results in better outcomes for disadvantaged groups or individuals.

The findings of this study have implications for public health policy in relation to the health of Aboriginal and Torres Strait Islander populations. In Australia, the health needs of Aboriginal Australians warrant special consideration because there is a documented gap in health status, access and outcomes between Aboriginal and non-Aboriginal Australians and there is a strong focus on closing this gap (Department of Health 2013). Recommendations in clinical practice guidelines would be expected to influence the outcomes of health service delivery to Aboriginal Australians if these guidelines are used by health practitioners who provide healthcare to Aboriginal and Torres Strait Islander populations. Yet this study found that Aboriginal populations were specifically given attention in fewer than half of the guidelines studied. This is despite the NHMRC standards for guidelines stating that it is mandatory that “issues relevant to Aboriginal and Torres Strait Islander communities, such as particular risks, treatment considerations or socio-cultural consideration, are identified and described” (NHMRC 2011). In light of the findings of this study, a public health policy recommendation might be that education programmes are delivered and evaluated for guideline developers and approvers to ensure that Aboriginal and Torres Strait Islander communities or patients are considered in all guidelines and, where appropriate, ATSI populations are prioritised in guidelines development processes. This finding is of further policy relevance because the Australian Commission on Safety and Quality in Health Care (2015) noted that for future guidelines to be prioritised for funding approval, “comment should be made on population groups for specific attention” and “Indigenous communities” was listed as one of these population groups for special attention. Yet, the newly released 2016 NHMRC standards for clinical practice guidelines make no reference to the need to consider Aboriginal and Torres Strait Islander populations. The impact of these seemingly conflicting requirements on how Aboriginal and Torres Strait Islander populations are considered in future clinical practice guidelines could be assessed with the use of the AGEL. Trends over time could be explored in future research with this lens.

Similarly, the 2011 NHMRC criteria also specified that “issues relevant to special-needs groups such as culturally and linguistically diverse communities or groups with low socioeconomic status should be identified”. This study found that people from low socioeconomic backgrounds were specifically considered in only 26% of the 74 guidelines and that culturally and linguistically diverse populations were considered in only 28% of guidelines. The extent to which specific groups are included could also be monitored over time, given the policy environment relating to clinical practice guidelines development referred to above.

From a public health policy perspective, the policy requirement to consider special groups is currently only relevant to guidelines approved or funded by the NHMRC. Most guidelines in this study were not developed or funded by the NHMRC, with only 15 guidelines being approved by them. The others were developed by, for example, health professional bodies, other government bodies or non-government organisations. Previous Australian research has shown that guidelines will be used, even if not endorsed by the NHMRC (Gupta et al. 1997a), provided the source is considered credible. In addition, with new mechanisms for dissemination of guidelines being developed by other guideline development bodies, such as the

“Cancer Guidelines Wiki” (Cancer Council Australia 2016) or algorithms in software for clinicians, it is possible that such guidelines will be used without NHMRC approval. Given that over half the guidelines were developed either by multidisciplinary non-government organisations or by a specialty society or medical college, this research suggests that non-government organisations that develop clinical practice guidelines in National Health Priority Areas, such as the National Heart Foundation or Asthma Foundation, might benefit from specifically targeted efforts directed towards incorporating equity considerations and the needs of disadvantaged groups into guidelines. There is also a need to ensure that these organisations and their members understand why special populations should be considered, how systematic reviews can be appraised to consider socioeconomic and ethnic/cultural stratifiers and how recommendations relating to special populations can be included in guidelines.

A specific area of concern for public health policy was identified in this research. Very few clinical practice guidelines in the study sample from the most common National Priority Area (cancer) considered equity and socioeconomic determinants. Only six of 26 cancer guidelines referred to socioeconomic determinants. Yet cancer is a significant public health issue in Australia. The estimated number of new cancer cases diagnosed in Australia in 2017 was 134,174 (Cancer Australia 2017) and the 31-year prevalence of all cancers was estimated by the Australian Institute of Health and Welfare in 2012 to be one million persons (Australian Institute of Health and Welfare 2014). Moreover, there is extensive evidence for socioeconomic inequalities in cancer incidence, mortality and survival (Merletti et al. 2011). The infrequent consideration of equity and socioeconomic determinants identified in this research has implications for public health policies relevant to non-government organisations and professional bodies which develop clinical practice guidelines focusing on cancer in Australia. Specifically, there is scope for public health policy change in this area, either by recommending or requiring these cancer organisations to include important considerations related to equity and disadvantage through guideline approval processes or through policies for funding such organisations to develop guidelines in the future. In a similar vein and as discussed previously, there is a strong public health policy focus in Australia on “Closing the Gap” in health status between Aboriginal and Torres Strait Islanders and the overall Australian population, including in cancer incidence and mortality (Commonwealth of Australia 2016). However, this research identified that only nine of the 26 cancer guidelines (35%) specifically mentioned Aboriginal and Torres Strait Islander populations. This points to the need for non-government organisations (e.g. Cancer Council Australia) and multidisciplinary health professional bodies (e.g. Clinical Oncological Society of Australia) to set their policies and standards to consider more explicitly and address the needs, outcomes and cultural requirements of Aboriginal and Torres Strait Islander populations in their guidelines development processes.

As mentioned earlier in this discussion, none of the guidelines reviewed made specific mention of using the *World Health Organization Handbook for guideline development* (World Health Organization 2012). However, in this study, the AGEL allowed for quantification of key features derived from this handbook and relating to the integration of equity, human rights and gender into clinical practice guidelines (World Health Organization 2012). Overall in these guidelines, there was poor compliance with the principles specified. Specifically, this study identified that only one-third of guidelines considered the potential for difference in uptake and benefits of interventions as a result of social position. Only 19% of guidelines showed evidence that systematic reviews used to inform guideline development explicitly described the potential effect of interventions across the social gradient and only nine guidelines specifically conveyed clear messages with respect to equity or social determinants as intent. Furthermore, although the World Health Organization guidelines place emphasis on declaration of conflict of interest by guideline developers and individuals in guidelines development teams, only 47% of guidelines in this study had a declaration of conflict of interest. These findings are consistent with the findings of other Australian studies (Buchan et al. 2010; Ghersi and Anderson 2015) and have implications for public health policy in that the study has identified a need for a strengthening of requirements to document conflicts of interest in guidelines development processes, as proposed by the World Health Organization.

The frameworks used in the development of a guideline are relevant to future policy development around clinical practice guidelines. This study found that most of the guidelines reviewed did not specify a known framework or approach for developing the clinical practice guideline. Of the 19 guidelines for which a framework was used, 12 made reference to the NHMRC standards for guideline development (NHMRC 1999b; NHMRC 2011), while others referred to standards for methodological quality such as the AGREE instrument (Brouwers et al. 2010a, 2010b, 2010c; Makarski and Brouwers 2014) or the ADAPTE standards for adapting existing international guidelines (ADAPTE Collaboration 2009). However, it is of note that no guidelines made reference to other frameworks or guidelines which focus on health equity or socioeconomic determinants, including the INCLEN equity in guidelines lens (Dans et al. 2007), the PROGRESS lens for systematic reviews (O'Neill et al. 2014) or the NHMRC document, *Using socioeconomic evidence in clinical practice guidelines* (NHMRC 1999a). While there are no comparative data for use of these instruments in other international guideline sets, this research has identified that in Australia, in national health priority areas, these key relevant frameworks have not been used.

In this study, the methodological quality of the guidelines was variable, with 24 of the 74 guidelines rated as poor with a score of 7 or below (maximum score 14), using the validated iCAHE instrument to assess guideline quality (Grimmer, 2014). This is relevant and consistent with other studies of Australian guidelines that have also demonstrated poor quality (Ward and Grieco 1996; Buchan et al. 2010; Ghersi and Anderson 2015). This finding, together with the other omissions in clinical practice guidelines relating to equity, socioeconomic determinants and special populations, suggests that further policy consideration is warranted on how best to improve the standard of guideline development more broadly, including but not limited to consideration of equity and socioeconomic determinants. At an individual guideline level, Machingaidze et al. (2015) noted that team training requirements regarding guidelines should be identified and addressed before starting clinical practice guideline development. Further intervention research would be beneficial in evaluating what is most effective in improving the visibility of equity and socioeconomic determinants within the context of improving the overall quality of guidelines in the future.

5.2 Limitations of the research

There are potential limitations in this research. The limitations in relation to validity, reliability and usability testing were discussed in Chapter 3 and will not be reconsidered here. The other limitation relates to the representativeness of the findings. Specifically, it is not possible to extrapolate the findings of this study to other non-national health priority guidelines on the NHMRC Clinical Practice Guideline Portal or to international settings. In this study, guidelines were systematically selected using a documented process to identify the study sample. The findings are only relevant to these guidelines, although as has been discussed in this Chapter, some findings are consistent with those in other studies. There is also the possibility that other guidelines on the NHMRC's Clinical Practice Guidelines Portal, such as those not in the National Health Priority Areas, may have different approaches to inclusion of equity or socioeconomic determinants, although there is no clear indication as to how such a selection bias might manifest in this regard. Guideline handbooks which covered a range of topics were also excluded from the study sample and it is possible that such compilation CPG handbooks may have been more likely to include consideration of equity, socioeconomic determinants than single topic guidelines, because, for example, they focussed specifically on service delivery for ATSI populations.

Another limitation is that it is not possible to ascertain whether there has been improvement in guidelines developed in 2015 and 2016. More recent developments in Australia may have led to improvement in the consideration of equity and socioeconomic guidelines. These developments include publication of work by Ghersi and Anderson questioning whether Australia's clinical practice guidelines "could be trusted" (Ghersi and Anderson 2015, p. 8) and the paper by the Australian Commission on Safety and Quality in Health Care on prioritising clinical practice guidelines (Marshall 2015), which specified the importance of considering the needs of disadvantaged populations. It is also not possible to extrapolate these findings to guideline sets of other jurisdictions, such as the United Kingdom, where the process of guidelines development is structured by the National Institute of Clinical Excellence, or Canada, from where the PRISMA-2012 equity extension for systematic reviews was initially derived (Burford et al. 2013). However, the AGEL or aspects of it could be used or modified in these settings to audit existing guidelines or assist future clinical practice guideline development bodies to consider equity in those guidelines.

5.3 Recent developments

It is of relevance that other international groups have been considering this issue recently. In a paper by Welch et al. (2017), published after conduct of this research and just prior to submission of this dissertation, the authors also searched guidelines methodology papers, conceptual papers and examples of guidelines which considered health equity specifically. This review is being considered by the GRADE (Grades of Recommendation Assessment, Development and Evaluation) working group, who are inviting comments. The authors concluded that clinical guidelines have a role in promoting health equity by considering equity in the process of guideline development and they forecast future methodologic work in this area. The authors then developed consensus-based guidelines with a working group to address health equity when rating the quality of evidence. These guidelines followed a different approach to developing consensus-based guidelines for including equity considerations in clinical practice guidelines than that used in this dissertation to develop the AGEL. Welch et al. (2017) used consultation with an existing working party and experts rather than a policy Delphi process, with international contributors to the work. The authors proposed five methods for explicitly addressing equity, three of which are similar to those included in the AGEL Version 3. These methods were using health equity as an outcome; considering patient outcomes related to equity; and assessing indirectness of evidence to disadvantaged populations. The other two methods "assessing differences in the relative effects size" and "assessing differences in baseline risk and the differing impacts on absolute effects" (Welch et al. 2017) were not included in the final version of the AGEL, although included in earlier versions. They are epidemiologic concepts and it is postulated that they are difficult for guideline developers to implement in the absence of good quality data from systematic reviews. It is also noted that these methods were proposed in the NHMRC document *Using socioeconomic evidence in clinical practice guidelines* (NHMRC 1999a) yet this document was not referenced in any of the 74 guidelines studied in the sample. Accordingly, further evaluation of Welch's methodology in terms of the practical implementation of the recommendations by guideline developers may be warranted to assess the impact of these guidelines.

5.4 Further public health policy relevance

As explained in this dissertation and pointed out by others (NHMRC 1999a; Harris et al. 2003; Dans et al. 2007; Shi et al. 2014; Welch et al. 2017), guidelines have the potential to reduce or increase inequity and to affect disadvantaged populations in a positive or a negative manner. This study has highlighted that in most Australian guidelines studied, equity and socioeconomic determinants were not considered. If they were mentioned, it was in a cursory manner without specific reference to the values underpinning the inclusion of equity and without considering social stratifiers in making recommendations in the clinical practice guidelines. The study has also found that existing tools which might influence the consideration of equity, socioeconomic determinants of health or disadvantaged populations, such as NHMRC's *Using socioeconomic evidence in clinical practice guidelines* (NHMRC 1999a), were not used consistently or to maximal effect in Australian clinical practice guidelines in national health priority areas. This study has therefore identified a gap in the visibility of equity and socioeconomic determinants in key guidance that affects health care delivery and patient care. The gap identified by this research has implications for future guideline developers. Importantly, the research findings also have implications for policies and standards developed by the NHMRC, which funds the development of some guidelines and is responsible for approving a number of national guidelines. Specifically, to ensure that new clinical practice guidelines include consideration of socioeconomic position and address the needs of special populations, the planned revision of the NHMRC standards for guidelines could flag that equity, human rights, and socioeconomic determinants must be specifically considered. In addition, such standards could specify how and why special populations, including Aboriginal and Torres Strait Islander populations, should be considered and where gaps in knowledge exist these could be flagged. Further, peak health bodies such as the non-government organisation Cancer Australia frequently develop clinically important guidelines which are often endorsed by the NHMRC. There is scope for a discourse with organisations such as this as to how they value equity and whether socioeconomic considerations can be routinely included in their work. In addition, good quality guidelines have the potential for adaptation for other environments or for contextualising the guidance by addressing implementation issues in such environments, including in international settings (Dizon, Machingaidze and Grimmer, 2016). Guidelines which consider equity, and in particular, those which systematically review the evidence about stratifiers and socioeconomic factors on health outcomes in making recommendations, may therefore have international public policy relevance if there is uptake of such guidelines, and these can be tailored to other countries or populations.

Of further relevance to public health policy, well-designed and credible guidelines tools can assist in clinical practice guideline development and ensure that critical factors are taken into consideration so as to improve outcomes of health care interventions. In this regard, the fields developed for the AGEL could be used or modified to be a checklist or aid for guideline developers to ensure that they have considered such factors. These fields could potentially be further tested or modified to provide a checklist for guideline developers, the NHMRC (for approval of guidelines), or the Australian Commission on Safety and Quality in Health Care, (which will be responsible for funding guidelines). Importantly, highlighting the findings of this study to guideline development organisations, guideline developers and consumers groups might result in the potential for equity, socioeconomic determinants and human rights to be considered in future guidelines developed by these bodies.

5.5 Dissemination plan

As part of the Doctorate of Public Health dissertation, it is necessary to describe actions demonstrating that the research will be, or has been, disseminated so that it can incorporated into public health policy or practice. The results of this research have been disseminated in a number of ways. First, a poster on the research was presented at the Guidelines International Network Conference in Philadelphia, in September 2016. This was an international meeting of approximately 500 guidelines developers, users, public health policy makers and health services personnel and the research was well received and discussed by guideline developers and users.

An oral paper was presented at the World Congress of Public Health international conference in Melbourne, in April 2017, attended by international public health professionals. A paper was also delivered in June 2017 at the Sydney Local Health District Research Innovations Symposium. Sydney Local Health District is the researcher’s place of work, and the symposium aimed to showcase current research with a view to translating research into practice. This was attended by 1000 staff including clinicians, policy makers, health executives and public health professionals.

Further dissemination of these research findings is planned. An abstract reporting the findings has been accepted for a poster in the “Health Equity” stream of the International Society for Quality in Health Care conference in London, October 2017. This conference attracts approximately 1000 international health care professionals who work in a range of areas, and it focuses on improvement of quality and outcomes of health care. An abstract has also been submitted to the NHMRC’s 2017 Research Translation Symposium meeting. The focus of this year’s meeting is on research relating to the health of Aboriginal and Torres Strait Islander populations, with a view to translating research into practice. Such a paper will have public health relevance to this topic, firstly because clinical practice guidelines are an important tool for translating clinical research into practice, and secondly because this research demonstrated a gap in the consideration of the needs of Aboriginal and Torres Strait Islander populations in most guidelines. A manuscript to be submitted for the peer reviewed publication, the *Australian and New Zealand Journal of Public Health*, is currently in preparation.

Finally, as a result of this research, the researcher was invited by the NHMRC to be a member of its SToRE Advisory Group (Synthesis and Translation of Research Evidence) which is developing an updated handbook for clinical practice guidelines to assist developers in producing guidelines which would then be suitable for endorsement by the NHMRC. The updated guidance will now include a chapter about equity and there will be a direct opportunity through this advisory committee to introduce this research, its findings and implications for public health policy to this NHMRC committee. A copy of the AGEL Version 3 and a copy of this dissertation will be provided to the NHMRC SToRE Advisory Group upon acceptance of this dissertation. As required as part of this dissertation, a briefing note summarising this research for the “target constituency”, which in this case is the NHMRC SToRE advisory committee, has been developed, and is presented at Appendix 6. Given that the highest proportion of guidelines were cancer guidelines, and this research demonstrated that most guidelines did not consider equity, socioeconomic determinants or special populations, this briefing note will also be provided to the

Federal government body, Cancer Australia, with a view to dissemination of the results among the constituent groups which develop cancer clinical practice guidelines, such as non-government organisations and health professional bodies.

5.6 Summary

This research has added new knowledge about clinical practice guidelines by developing a lens with sound psychometric properties for assessing quantitatively the visibility of equity and socioeconomic determinants in Australian clinical practice guidelines. The lens has potential for further adaptation and more extensive psychometric testing and for adaptation in other jurisdictions. Of relevance to public health policy, and as has been explained in this dissertation, the AGEL, or parts of it, could be used prospectively to assist in the inclusion of equity and socioeconomic determinants in future guideline development in Australia. The research also has implications for public health because it has identified for the first time that the majority of important Australian clinical practice guidelines in key National Health Priority Areas did not appear to consider equity and socioeconomic determinants. In particular, despite the NHMRC stating that specific populations should be considered in guidelines development and the national focus on “Closing the Gap” in health status between Aboriginal and Torres Strait Islander populations and the overall Australian population, Aboriginal and Torres Strait Islander populations were considered in less than half of the guidelines studied. It is of public health policy relevance that guidelines were more likely to consider Aboriginal and Torres Strait Islander populations when there was consumer involvement in guideline development, if the guidelines followed the NHMRC standards for guidelines, or if the overall methodological quality of the guidelines was high. Such findings point to a stronger policy emphasis on use of these national standards for all Australian clinical practice guidelines development. The findings also add weight to existing arguments for requirements to include consumers in clinical practice guidelines development.

This research found that the 74 guidelines covering National Health Priority Areas were of variable quality and that explicit reference to equity and socioeconomic determinants in them was not significantly associated with overall methodological quality of the guideline. This study also identified that it is feasible and possible to include equity, socioeconomic determinants and consideration of special populations, as noted in specific guidelines which achieved this successfully and were identified through this systematic approach. In the discussion section of this dissertation, the implications for further research and for public health policy formulation have been discussed. There has already been dissemination of this research to target audiences through conference presentations. Other planned avenues for dissemination of research have been outlined in this dissertation.

References

Guidelines

List of 74 guidelines included in the content analysis of clinical practice guidelines from the Australian Clinical Practice Guidelines Portal, available on the National Health and Medical Research Council Clinical Practice Guidelines Portal at https://www. clinicalguidelines.gov.au

1. Abuse and violence. Working with our patients in general practice (4th edition). Royal Australian College of General Practitioners, 2014.
2. Alcohol and other drug withdrawal: practice guidelines. Turning Point Alcohol and Drug Centre Victoria, 2012.
3. Asthma and allergy: an information paper for health professionals. National Asthma Council, 2012.
4. Asthma and healthy living. An information paper for health professionals. National Asthma Council, 2013.
5. Asthma and the over 65s. An information paper for health professionals. National Asthma Council, 2013.
6. Asthma and wheezing in the first years of life: an information paper for health professionals. National Asthma Council Australia, 2012.
7. Australian and New Zealand Clinical Practice Guideline for Prevention and Management of Venous Leg Ulcers. Australian Wound Management Association Inc./ New Zealand Wound Care Society, 2011.
8. Australian and New Zealand guideline for hip fracture care: improving outcomes in hip fracture management of adults. Australian and New Zealand Hip Fracture Registry, 2014.
9. Australian Diabetes Foot Network: management of diabetes-related foot ulceration – a clinical update. Australian Diabetes Foot Network, Australian Diabetes Society, 2012.
10. Australian Guidelines for the treatment of acute stress disorder and posttraumatic stress disorder. Australian Centre for Posttraumatic Health, 2013.
11. Building healthy bones throughout life: an evidence-informed strategy to prevent osteoporosis in Australia. Osteoporosis Australia. Individual authors, 2013.
12. Cancer pain management in adults. The Australian Adult Cancer Pain Management Guideline Working Party, 2013.
13. Cardiovascular disease: revascularisation. Kidney Health Australia, 2013.

14. Cardiovascular effects of blood pressure lowering in patients with chronic kidney disease. Kidney Health Australia, 2013.
15. Clinical guidance for responding to suffering in adults with cancer. Cancer Australia, 2014.
16. Clinical guideline for the prevention and treatment of osteoporosis in postmenopausal women and older men. Royal Australian College of General Practitioners, 2010.
17. Clinical guidelines for the physical care of mental health consumers. University of Western Australia, 2010.
18. Clinical guiding principles for sick day management of adults with type 1 and type 2 diabetes. National Diabetes Services Scheme, 2014.
19. Clinical practice guideline for the management of borderline personality disorder. NHMRC, 2012.
20. Clinical practice guideline: multiple myeloma. The Myeloma Foundation of Australia, 2011.
21. Clinical practice guidelines for surveillance colonoscopy. Cancer Council Australia, 2011.
22. Clinical practice guidelines for the management of adult onset sarcoma. Cancer Council Australia, 2013
23. Clinical practice guidelines for the management of locally advanced and metastatic prostate cancer. Cancer Council Australia/ Australian Cancer Network, 2010.
24. Clinical practice guidelines for the management of overweight and obesity in adults, adolescents and children in Australia. NHMRC, 2013.
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26. Clinical practice guidelines for the psychosocial care and bereavement support of family caregivers of palliative care patients. Centre for Palliative Care/Beyondblue, 2010.
27. Clinical practice guidelines for the treatment and management of endometrial cancer. Cancer Council Australia, 2011.
28. Clinical practice guidelines. Depression and related disorders, anxiety, bipolar disorder and puerperal psychosis in the perinatal period. Beyondblue, 2011.
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32. Diabetes management in general practice. Diabetes Australia/Royal Australian College of General Practitioners, 2011.
33. Evidence-based practice guidelines for the dietetic management of adults with pressure injuries. Trans-Tasman Wound Care Group, 2011.
34. Evidence based practice guidelines for the nutritional management of adult patients with head and neck cancer. Clinical Oncological Society of Australia, 2011.
35. Evidence-based guidelines for the management of hip fractures in older persons: an update. Individuals, 2010.
36. Fertility preservation for AYAs diagnosed with cancer – guidance for health professionals. Clinical Oncological Society, 2011.
37. First line chemotherapy for the treatment of women with epithelial ovarian cancer. Recommendations for the use of first-line chemotherapy for the treatment of women with epithelial cancer. Cancer Australia, 2014.
38. Follow up of women with epithelial ovarian cancer. Cancer Australia, 2012.
39. General practice management of type 2 diabetes. RACGP, 2014.
40. Guide to management of hypertension. Heart Foundation. 2010.
41. Guidelines for screening, assessment and treatment in problem gambling. Monash University/University of Melbourne, 2011.
42. Guidelines for the diagnosis and management of Brugada syndrome. The Cardiac Society of Australia and New Zealand, 2011.
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47. Guidelines for the diagnosis and treatment of malignant mesothelioma. Asbestos Disease Research Institute, 2013.
48. Guidelines for the management of absolute cardiovascular disease risk. National Vascular Disease Prevention Alliance, 2012.
49. Guidelines for the prevention and management of chronic heart failure in Australia. Heart Foundation, 2011.
50. Managing allergic rhinitis in people with asthma. National Asthma Council Australia, 2013.

51. National evidence based clinical care guidelines for type 1 diabetes in children, adolescents and adults. Australian Paediatric Endocrine Group/Australian Diabetes Society, 2011.
52. National guidelines for medication-assisted treatment of opioid dependence. National Drug Strategy Committee, Commonwealth of Australia, 2014.
53. Peri-operative diabetes management guidelines. Australian Diabetes Society, 2012.
54. Practice guidelines for treatment of complex trauma and trauma informed care and service delivery. Adults Surviving Child Abuse, 2012.
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58. Recommendations for staging and managing the axilla in early (operable) breast cancer. Cancer Australia, 2011.
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Appendix 1

National Institute of Clinical Excellence Case Study

Independent and “fair”: is the National Institute for Health and Clinical Excellence holding itself back on making inroads into healthy public policy for equity?

A case study including a pilot study of a using guideline equity lens on NICE guidelines

Leena Gupta, 2009

Introduction

The National Institute for Health and Clinical Excellence (NICE) is an independent organisation “responsible for providing national guidance on promoting good health and preventing and treating ill health”[1] in the United Kingdom (UK). The organisation is funded mostly by the UK Department of Health, the annual grant for 2007-8 being £33.4m[2]. It employs 270 staff, and has been noted to have a highly skilled workforce, particularly in guidance development and community consultation[3]. NICE also auspices many advisory groups, Councils, and sub-committees working on guidance development [4]. NICE’s Centre for Public Health Excellence is responsible for producing guidance (referred to as “guidelines” in Australia), aimed at “promoting good health and preventing ill health for those working in the NHS, local authorities and the wider public and voluntary sector”[1].

In this case study I will, to set the context, firstly describe how NICE structures itself as an organisation to contribute to healthy public policy. I will do this by appraising NICE’s documented activities and organisational capacity against a framework for healthy public policy developed by Draper[5]. Secondly, in order to explore how NICE, as an organisation, addresses equity issues in guidelines, I will review the public health guidance that NICE has produced to date, to examine how the guidance includes notions of equity and to identify the drivers for their inclusion. In doing this, I will illustrate how despite being an organisation with a high budget, a highly capable workforce, a structured consultation process with external stakeholders, and a governance body which prioritises equity, the organisation still appears to hold itself back from maximising its contribution to healthy public policy for equity.

Other areas of NICE’s work include clinical guidelines development, technology assessment, international consultancy and coordination of National Collaborating Centres for clinical guidelines[4]. These will not be covered in this case study, as they relate mostly to clinical or technological interventions.

The organisational context: how is NICE structured to contribute to healthy public policy for equity?

An organisational appraisal: materials and method

Several frameworks are available to assess how an organisation contributes to healthy public policy[6,7,8,9,10.] All frameworks emphasise multi-sectoral activity, a conducive organisational culture, together with community driven and collaborative approaches in order to address health inequalities due to social gradients[11]. In this paper, I will apply the framework developed by Draper[5,] which identifies six characteristics of healthy public policy, listed in Figure 1.

Figure 1: Six features of healthy public policy

- Public health issues are multi-sectoral and involve a range of interest groups.
- Healthy public policy should involve commerce and industry, voluntary organisations and all tiers of government.
- International in scope.
- The aim should be educational and persuasive rather than dictatorial or puritanical and should aim to make healthy choices the easy choices.
- Action for healthy public policy takes many forms, through formally organised lobby groups or the actions of local community health initiatives.
- Healthy public policy is an intrinsically political activity.

Adapted from: Draper, 1991[5]

This framework was selected because it was feasible to apply to the analysis method described below. Secondly, it is comprehensive, in that it encompasses most of the attributes of healthy public policy referred to in other frameworks. I also looked specifically at how organisational commitment was reflected in the document, as this is not specifically covered by Draper's framework, but included in others[6,7,8,9].

I undertook a content and themes analysis of all publicly available documents relating to NICE . These included: all documents and information made available on its extensive website[1] such as annual reports, technical reports; minutes of Board meetings and citizen councils; all published papers and grey literature in the past 10 years produced by NICE or other organisations about NICE; and all print media articles over the past 10 years (identified through Factiva). Each document was reviewed, and information relevant to each aspect of the framework was categorised manually.

Findings of the organisational appraisal and interpretation

"Multisectoral and involving a range of interest groups"

"Involve commerce and industry, voluntary organisations, community and all levels of government"

NICE is governed by a sixteen person Board appointed by the UK Minister for Health, to which reports a senior management team and various sub-committees[2]. Also reporting to the Board are a "Partner's Council"[12], comprising members drawn from organisations interested in NICE's work - thus involving industry, professional organisations, non-government organisations, community organisations, and interest groups. There is also a "Citizens Council", which comprises 30 individual citizens *"from all walks of life"*[2] who can be consulted on a range of matters. Further, guidance development has proscribed consultation processes involving the types of stakeholders listed in Draper's framework[2,13]. In particular, where guidance involves other sectors, a representative of that sector is on the guidance development group. However, the content analysis identified that "multisectoral involvement" of such groups did not encompass intersectoral involvement at a political level, nor at the more senior levels of the bureaucracy, which are more likely to effect change[14]. Hence, there is less likelihood that those participating from the other sectors might have enabled policy change in those sectors[14]. Further process evaluation to examine the nature of intersectoral representation is warranted, in order to improve NICE's effectiveness in healthy public policy.

"Organisational commitment to equity"

The contents and themes analysis identified evidence of a strong organisational commitment to equity and healthy public policy. Several examples were identified: the NICE Board's Statement of Commitment to addressing equity[2]; the existence of Citizens Panels[4], the explicit documentation of the social values of the organisation[15], and the inclusion of "addressing equity" in job descriptions of chairs of advisory bodies[16]. In addition, the NICE Equality Scheme and Action Plan[16] specifies that it will *"work on techniques for applying an equity perspective to public health topics"*. Guideline review panels, which are "*where 4-5 members pay particular attention to how the guidelines development group has responded to any comments during consultation*" have also specifically focussed on equity[17]. Overall, these findings support the widely held view[3,18] that NICE is both a collaborative and participatory organisation[6] with an organisational culture[7] that supports consultation and community involvement.

“International in scope”

Document review identified several ways in which NICE has structured itself to be international in scope. It has an international consultancy arm[4,19] through which NICE can apply expertise, usually in guidance development, in other countries for a fee. Of greater relevance to international healthy public policy, has been NICE’s influence through its technical leadership in guidance development processes[20]. Many other countries have shown interest in emulating NICE’s approach[3,18,21,22]. While the analysis identified one example of international advocacy for equity, a paper written to support the WHO Commission on Social Determinants of Health[11],” *The social determinants of health: Developing an evidence base for political action*[23]*”*, there is little other evidence of an international equity agenda.

“Educational and persuasive”

Despite NICE being an organisation which produces guidance, the contents and themes analysis did not find NICE describing itself as an educational organisation, nor a “persuasive” organisation. Rather, it promotes itself as providing “fair” guidance[2] which organisations and individuals can use to inform public health approaches[24]. However, in developing and producing this guidance, it could be argued that the organisation is inherently persuasive because of the prominence given to it in the UK by the National Health Service (NHS). Further, while NICE does not explicitly state its educational objectives, it has played a role in capacity building for equity in the NHS: specifically, NICE has taken a leadership role in the Primary Care Trust (regional health authorities) by developing tools and educational material to improve capacity in conducting health equity audits[25,26.]

“Action for healthy public policy takes many forms, through organised lobby groups or the actions of local community health initiatives. “

“It is intrinsically political”

In its Equality Action Plan,[16] NICE has forewarned of future activities to involve the community in decision-making. These include a planned review of methods for communicating with hard to reach groups[16] and a strategy for encouraging suggestions from a broader range of people and organisations on guidelines. In addition, NICE’s Board meetings are open to the public[2]. It has a “patient and public involvement programme” to complement the work of “partners” and “citizens” councils. The theme that emerged from document review is that partnerships were predominantly comprised of input into decision-making. As such, the nature of these partnerships appeared to be “cooperative”, rather than "collaborative" (defined by VicHealth, *"as enhancing the capacity of the partner for mutual benefit and common purpose"*[27]). Qualitative research with partners to explore the extent of community involvement, their views and how, in turn, the nature of the partnership might contribute to policy change for equity would be of interest.

For clinical guidelines, NICE has been successful in translating its guidance to action through National Collaborating Centres (NCCs), which bring together organisations *to "look at implementation and practice change, and focus on initiatives in the community that have the potential for change in clinical practice through such collectivities"*[2]. The content analysis did not find any NCCs for public health issues. Reasons for this were also not identified. It may be that the nature of public health practice is such that this type of collectivity would be "intrinsically political", something from which NICE appears to have shied away[3.] To elaborate, while NICE as an organisation positions itself to take into account the views of, and actively consult advocates or interest groups, the organisation has gone to great lengths to distance itself from political processes, particularly in relation to resource allocation decisions[23], rather focussing on the rigour of its guidance development processes when any political debate occurs. The independence of the organisation is something that is stressed: *"we have to maintain our independence of thought and process"*[3] resulting in the organisation not being overtly politically active.

Yet there is a dichotomy here because, as demonstrated earlier, the organisation has taken a political stance on equity via its Board,[2] in NICE's work for the WHO Commission on Social Determinants[23] and by releasing a strong statement of its values, *Social Values Judgments, Principles for the Development of NICE Guidance*[15.] This document describes the principles that NICE should follow when applying social value judgments in decision-making. It explicitly states fairness, human rights, utilitarianism, inclusiveness and promoting equity as important principles and is consistent with a "long term view" throughout. However, in terms of healthy public policy, the organisation has chosen to stop at that point. Specifically, while the actions of lobby groups or community groups appear to inform guidance development – there is little evidence from document analysis that these same groups have any ownership of the guidance nor advocate for equity in implementation. NICE also does not appear to draw attention to significant systemic barriers to addressing inequity, but rather embeds recommendations or evidence gaps in its guidance without political involvement or advocacy. Further research on how this dichotomy impacts on evidence translation in relation to public health guidelines and on outcomes related to addressing inequity could elucidate this further.

Public Health Guidance

The guidance development process

NICE states that its public health guidance *"makes recommendations for population and individuals on activities, policies and strategies that can help prevent illness or improve health.*[28]*"* NICE has completed guidance on 19 topics under the auspices of NICE's Centre for Public Health Excellence[29]. More recent guidance topics include: improving the health of school children, nutrition, physical activity, smoking cessation, community engagement, and some occupational health topics. A detailed manual also exists for how guidance should be produced and the consultation processes involved[30].

How NICE incorporates notions of equity and healthy public policy for equity in its public health guidance

Public health guidance audit: methods and materials

In order to assess how evidence about equity is included in public health guidance developed by NICE, I developed an audit tool which was applied to each of 19 public health guidance documents developed by NICE between the period April 2007 to March 2009. The audit tool was designed to elicit specific information about the following:

- whether interventions addressing inequity are included in the guidance, their location within the guidance (background information, guidance recommendations, guidance interventions, recommendations for further research) and whether, overall, equity is given policy emphasis within the guidance,
- whether the interventions are primarily medical, behavioural or socio-environmental (structural);
- what drivers were mentioned as being relevant to inclusion of considerations about equity and social determinants of health in the guidance;
- were the following requirements of healthy public policy for equity, as described by Hancock[7], met in the guidelines: is a long-term view evident, is the need for political commitment, intersectoral processes/structures/, public support, community driven practices, multifaceted strategies, organisational culture change, mentioned or addressed; and
- whether primary research incorporating data on social gradients in relation to the topic was used to inform the guidance recommendations; whether the gaps in evidence in this area were noted.

The audit tool was developed by the author and pilot tested on three guidelines developed by other organisations. In order to maximise validity of the audit tool, questions were developed to minimise subjectivity, and where possible either to quantify or elicit responses about aspects that could be assessed more objectively by the one researcher (LG). The audit tool was also reviewed by another public health practitioner prior to applying them to the guidance. A copy of the audit tool is available from the author on request. The results of the audit were collated manually and key themes arising were reviewed within the context of the organisational appraisal.

Public Health Guidance audit: findings and interpretation

The findings of the audit of public health guidance are in Table 1.

The review found that most, but not all, of the guidance mentioned the need to address inequity, although only about a quarter placed a policy emphasis on this. Mostly equity was mentioned in the background information, with only five guidance documents having specific interventions to address equity or social gradients in health. This is consistent with a strong behavioural emphasis in guidance topic selection: the majority of public health interventions were behavioural (ie risk factor modification, behaviour change) rather than structural, with two public health guidance documents being primarily therapeutic guidelines.

Table 1: References to equity, and requirements for healthy public policy for equity, in 19 NICE public health guidance documents, April, 2007- March, 2009[1].

FACTORS RELEVANT TO EQUITY AND HEALTHY PUBLIC POLICY	FREQUENCY OF INCLUSION IN 19 GUIDANCE DOCUMENTS
Reference to inequity in guidance	16
Reference to equity in*:	
Background information	15
Recommendation/interventions	5
Recommendations for further research	8
Are equity issues given policy emphasis in the guidance?	5
Domain for main interventions*	
Therapeutic	2
Behavioural	15
Socio-environmental (structural)	6
Drivers for inclusion of equity in guidance*	
• Consistent with national government or NHS policy	9
• NICE Board priority	1
• Specific NICE documents such as the "Social values statements", "Equity Action Plan"	2
• Human rights justification	0
• Evidence of impact of social gradient on the health issue/social intervention	4
• Civic responsibility	0
• Community requirement/feedback/request	0
• Other stakeholder requirement/feedback	0
Requirements of healthy public policy for equity mentioned*:	
• A long-term view	7
• Need for political commitment mentioned or addressed	0
• Intersectoral processes/structures	5
• Public support	1
• Community drives practices	1
• Multifaceted strategies	11
Primary research evidence on social gradient informed the guidance recommendations	4
Gaps in relation to data or research on social gradient and equity noted	8

*denotes that responses are not mutually exclusive

The appraisal of the public health guidance against the requirements for healthy public policy mirrored these findings, and was also consistent with the apolitical stance of NICE, as discussed earlier in this paper. While themes indicating a long-term view and multi-faceted strategies to address public health issues were evident in most guidance, themes around political commitment, community-driven practices and public support for interventions (criteria for healthy public policy noted by Hancock7)) were not evident. This suggests that the public health guidance produced by NICE is “public health policy”, rather than “healthy public policy”, an important distinction made by Hancock. This finding warrants further policy-oriented research within the organisation.

The drivers to address inequity identified were the need to conform to national (NHS) policy[31], and less frequently, evidence about social gradients in health. Only about a quarter of the guidance documents actually used primary research data incorporating evidence on social determinants of health in the background material. However, nearly half did refer to the need for more data in this regard. Interestingly human rights issues, civic responsibility or community expectations were not stated as drivers for addressing equity within the guidance. In addition, as found in the organisational appraisal, the absence of statements relating to political commitment and community support may be barriers to successful guidance implementation, irrespective of the quality of the guidelines. Further impact and outcomes research would clarify this in the future.

As the public health guidance process has not been subject to a programme evaluation to date, the impact of the guidance on equity indices, community support for their content, and their political impact would be of interest in any future evaluation, from a healthy public policy perspective. Further, the proposed Post-2010 Strategic Review of Health Inequalities in the UK[32] would be well placed to consider the role of NICE public health guidance in contributing to health equity outcomes targets.

Case study limitations

Some limitations in the interpretation of this case study warrant discussion. While methods for triangulation have been used, such as applying two different frameworks and using various sources of information to examine how the organisation functions, additional methods of data collection to supplement the document review might have maximised the validity of the findings. In particular, interviews with people who work with or for NICE, including members of the citizens Councils, and interviews with those in the NHS about NICE’s influence would provide further insight into how the organisation addresses equity. Their comments on the findings of the organisational appraisal and the public health guidance audit would also add to the reliability of its findings, by allowing for consideration of alternative perspectives and different cultural views on equity and evidence. It is also accepted that the choice of frameworks, and the thematic and contents analysis methodology used in both the organisational appraisal and public health guidance audit has an aspect of subjectivity. While the coding framework and audit questions were designed to reduce this, subjectivity could be further reduced by having a panel of reviewers code the findings of the thematic and contents analysis, and different frameworks could be applied to provide different perspectives.

Summary

NICE is a highly capable organisation with a large budget to deliver public health guidance. This case study has demonstrated its strong commitment to equity. Its organisational make-up, particularly its governance, consultation processes and partners drive and support this commitment. The organisation poises itself as an independent organisation and hence has been publicly unwilling to be politically active in promoting its guidance recommendations. Further, its public health guidance development processes do not necessarily require high level multisectoral support, possibly providing a structural impediment to successful guidance implementation.

While most guidance documents refer to equity, this is rarely emphasised. Guidance infrequently incorporates primary research data on inequity nor multisectoral or structural interventions more consistent with a “healthy public policy” approach. The case study illustrates a phenomenon whereby this internationally-lauded organisation, while contributing to public health policies in the form of guidance, may not necessarily be maximising its impact on healthy public policy. This augers for more research to validate these findings using methods other than document review, perhaps within the context of a programme evaluation or other national reviews, such as the proposed Marmot review on health inequalities in the UK. NICE’s approach to equity identified in this paper has implications for organisations such as the National Institute of Clinical Studies[33], which is part of the NHMRC in Australia, and in the US[34], which seek to emulate NICE’s processes. There are many elements of NICE’s approach to healthy public policy and its organisational capacity that would be useful to implement in other countries, if resources were made available. However, NICE’s stance on independence, and separation from political process and collectivities in public health, should also be considered by these organisations if they wish to maximise their impact on healthy public policy for equity.

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Appendix 2

Australian Guideline Equity Lens Version 1

DISCIPLINE OF PUBLIC HEALTH

SCHOOL OF MEDICINE

APPRAISAL INSTRUMENT: THE VISIBILITY OF "EQUITY" IN CLINICAL PRACTICE GUIDELINES

AUSTRALIAN GUIDELINE EQUITY LENS VERSION 1

Use this appraisal tool to evaluate each clinical practice guideline which is publicly available via the NHMRC National Clinical Guidelines Portal.

PART A: General information about the guideline

(1) What is the title of the guideline?

____

(2) What is the name of the guideline development organisation(s)/group(s)?

____

(3) Which of the following is the most relevant description of the primary guideline development groups(s)? [circle appropriate categories]

(a) Multidisciplinary non-government organisation (eg NHF, Cancer Council)

(b) NHMRC

(c) Other Federal Government body

(d) State health government

(e) Local health service

(f) Other government department

(g) Local government

(h) NACCHO / State affiliate / Aboriginal Community Controlled Organisation

(i) Medical College

(j) Specialty Society

(k) Nursing College

(l) Other health professional organisation

(m) Consumer organisation

(n) Other. Please specify:

____

____

____

(4) Which of the following is the most relevant description of the secondary or other guideline development groups(s)? [Circle the best one / or as many as apply?]

(a) Multidisciplinary non-government organisation (eg NHF, Cancer Council)

(b) NHMRC

(c) Other Federal Government body

(d) State government

(e) Local health service

(f) Other government department

(g) Local government

(h) Aboriginal Community Controlled Organisation

(i) Medical College

(j) Specialty Society

(k) Nursing College

(l) Other health professional organisation

(m) Consumer organisation

(n) Other. Specify:

____

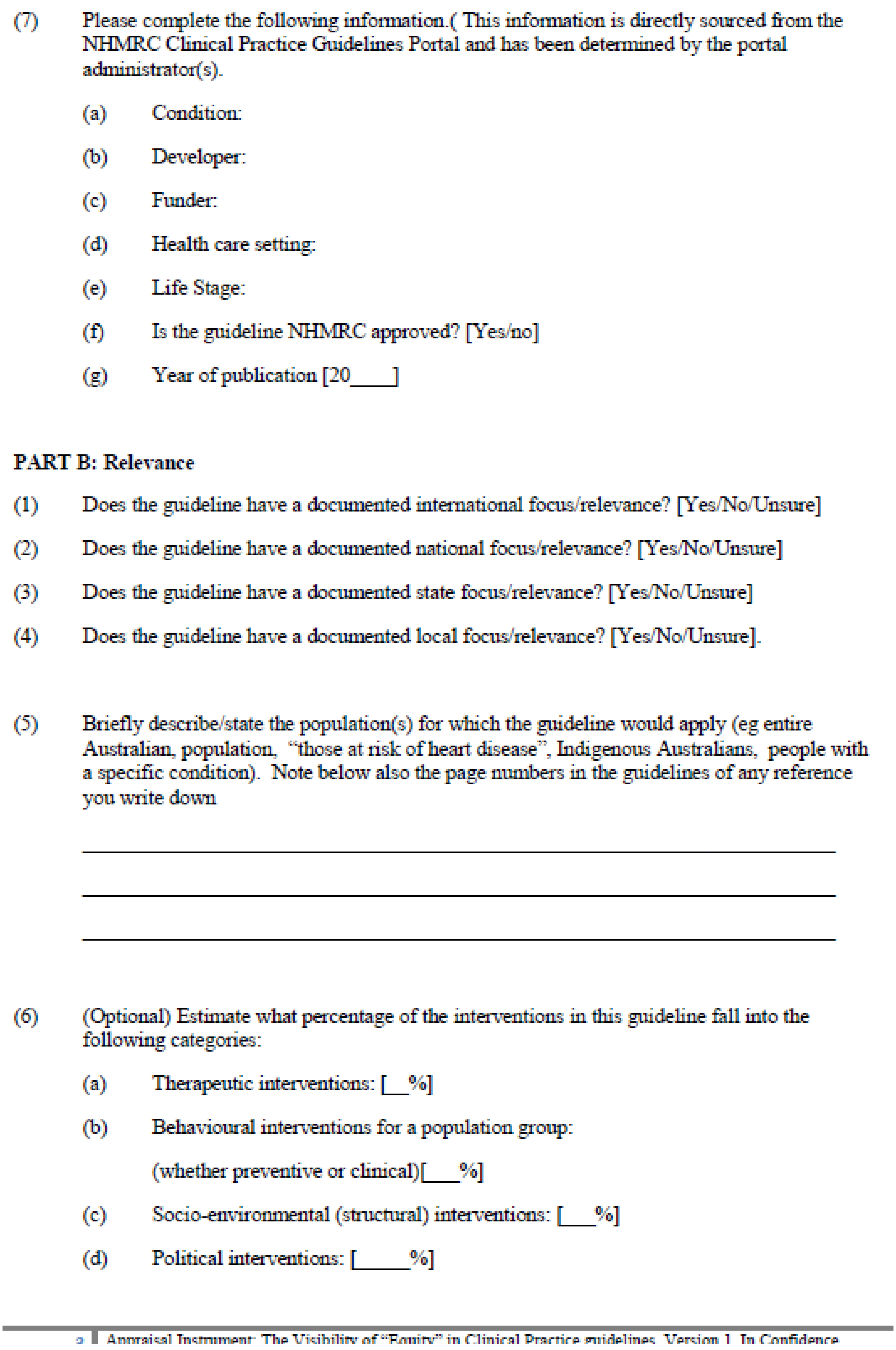
____

____

(5) What is the year of publication of guideline: [20____] or Not stated _____

(6) Has this guideline been revised since publication?

[Yes/no/not sure]– if so, in what year? [20_____]



(7) Please complete the following information.(This information is directly sourced from the NHMRC Clinical Practice Guidelines Portal and has been determined by the portal administrator(s).

(a) Condition:

(b) Developer:

(c) Funder:

(d) Health care setting:

(e) Life Stage:

(f) Is the guideline NHMRC approved? [Yes/no]

(g) Year of publication [20____]

PART B: Relevance

(1) Does the guideline have a documented international focus/relevance? [Yes/No/Unsure]

(2) Does the guideline have a documented national focus/relevance? [Yes/No/Unsure]

(3) Does the guideline have a documented state focus/relevance? [Yes/No/Unsure]

(4) Does the guideline have a documented local focus/relevance? [Yes/No/Unsure].

(5) Briefly describe/state the population(s) for which the guideline would apply (eg entire Australian, population, "those at risk of heart disease", Indigenous Australians, people with a specific condition). Note below also the page numbers in the guidelines of any reference you write down

____

____

____

(6) (Optional) Estimate what percentage of the interventions in this guideline fall into the following categories:

(a) Therapeutic interventions: [__%]

(b) Behavioural interventions for a population group:

(whether preventive or clinical)[___%]

(c) Socio-environmental (structural) interventions: [___%]

(d) Political interventions: [_____%]

(e) Other:

(7) What consumer/client representation is described in the guideline?

PART C: Quantifiable information

(1) Has specific reference in this guideline been made to the guideline being developed with reference to any particular framework or guide? eg AGREE instrument, NHMRC guidelines for guidelines - (as described in the guidelines development methods) [Yes/No].

(2) If yes, please list:- (note page numbers)

(3) Overall, to what extent has health equity, inequality or socioeconomic determinants impacting on health appeared to be a consideration in this guideline? [Choose which best applies]

(a) Not a consideration at all

(b) Considered a little

(c) Considered to a moderate extent

(d) Considered a lot

Provide page numbers in the guidelines to support this rating.

(4) a) Are there specific reference(s) in the guideline to the need to address inequity?

Yes/no/not sure. Specify details of this reference(s).

b) Are there specific reference(s) in the guideline to the need to address inequality?

Yes/no/not sure. Specify details of this reference(s).

(5) In which sections of the guideline are there references to inequity/inequality in:

(a) Background information? [Yes/No]

(b) Recommendation/interventions? [Yes/No]

(c) Recommendations for further research? [Yes/No]

(d) Other? [Yes/No]

(e) Comments, including wording in each section

(6) Has primary evidence on social gradient informed the guidance recommendations?

[Yes/No].

Comment: If possible, comment on whether the social gradient relates to being a predictor of the incidence of ill-health, or related to patterns of care or treatment responsiveness or other factor.

(7) Have gaps in relation to data or research on social gradient and equity been identified in the guideline's literature review, the guideline itself or elsewhere in the document?

[Yes/No]. Comment:

(8) What has been documented in the guidelines as policy drivers for inclusion of equity in these guidelines (if at all): [circle appropriate choice(s)]

(a) Consistent with government or other policy [Yes/No]

(b) Equity is a priority for the guideline development organisation [Yes/No]

(c) Human rights justification [Yes/No]

(d) Evidence of impact of social gradient on the health issue/social intervention [Yes/No]

(e) Civic responsibility [Yes/No]

(f) Community requirement/feedback [Yes/No]

(g) Other stakeholder requirement [Yes/No]

(h) NHMRC guidelines on socioeconomic determinants [Yes/No]

(i) Other

____

____

____

(9) To what extent are socioeconomic determinants of health taken into account into guidelines?

____

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PART D: DETAILED EQUITY ANALYSIS - *In this section, a framework analysis will be undertaken by the researcher, with the following general areas for consideration in relation to each of the guidelines. The framework analysis may identify specific dimensions which may also then be included in the previous sections of the appraisal tool.*

Health inequalities

Has the guideline looked at the potential for health inequalities in the guidelines topic?

If inequalities are identified – inequality of what? (health care access, health care provision, health care policy, outcome)?

What data is used to identify the potential for inequalities? How are these addressed?

Does the guideline identify any inequalities that are particularly unjust in relation to the health issue in question eg racial or gender inequalities.

How does it deal with these inequalities? ie inequality amongst whom?

Are there certain population groups that there is a need to ensure that inequality does not arise?

Has the guideline addressed these inequalities, and if so, how?

Opportunity and responsibility

Does the guideline afford "equality of opportunity" for the clients for whom the guideline is designed?

Does the guideline show evidence of equalising access to medical care

Does the guideline show evidence of equalising (life) opportunity?

To what extent does the guideline emphasise that individuals are personally responsible for health?

Does the guideline discuss or take into account social, environmental, economic factors/agents as disease factors or promoters of treatment?

Are there other themes may emerge as a result of the framework analysis.

PART E: APPRAISAL OF CRITERIA TAKEN FROM PREVIOUSLY DEVELOPED PAPERS (Dans et al, Tugwell et al.)

Application of the equity lens for guidelines as developed by *Dans et al*, - with equity gradients defined by PROGRESS (mnemonic): place of residence, race, occupation, gender, religion, education, socioeconomic status, social network and capital.

(1) Do the recommendations in the guidelines address a priority problem for disadvantaged populations? [Yes/No]. Comments:

____

____

____

____

____

____

(2) Is there a reason for the guideline developers to anticipate different effects of intervention in disadvantaged and privileged populations? [Yes/No]. Comments:

(3) Are the effects of the intervention valued differently by disadvantaged compared to privileged populations? [Yes/No]. Comments:

(4) Is specific attention given to minimizing barriers to implementation in disadvantaged populations? [Yes/No]. Comments:

(5) Do plans for assessing the impact of the recommendations, include assessing impact /outcome in disadvantaged populations? [Yes/No]. Comments:

Part E: NHMRC guidelines on using socioeconomic evidence in clinical practice guidelines

(1) Are the NHMRC guidelines on using socioeconomic evidence in clinical practice guidelines referenced? [Yes/No]

(2) Has the methods section mentioned that the literature has been searched for socioeconomic inequalities in the condition of interest or intervention? [Yes/No].
Comments/describe, including, add page number:

(3) Does the guideline present an analysis of the clinical issue related to socioeconomic position? [Yes/No]. Comments/details:

(4) Do the papers referenced show this analysis? [Yes/No]. If so, identify to what extent;

(5) Does the guideline report how the literature was searched to identify interventions that address barriers or opportunities for achieving equal health gains? [Yes/No].If so, specify how:

____

____

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____

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____

PART F: ANY OTHER RELEVANT INFORMATION/COMMENTS:

Appendix 3

Australian Guideline Equity Lens Version 2

Flinders
UNIVERSITY

DISCIPLINE OF PUBLIC HEALTH

SCHOOL OF MEDICINE

APPRAISAL INSTRUMENT: THE VISIBILITY OF “EQUITY” IN CLINICAL PRACTICE GUIDELINES

Version 2

Use this appraisal tool to evaluate each clinical practice guideline which is publicly available via the NHMRC National Clinical Guidelines Portal.

PART A: General information about the guideline

(1) What is the title of the guideline?

____

(2) What is the name of the guideline development organisation(s)/group(s)?

____

(3) Which of the following is the most relevant description of the primary guideline development groups(s)? [circle appropriate categories]

(a) Multidisciplinary non-government organisation (eg NHF, Cancer Council)
(b) NHMRC
(c) Other Federal Government body
(d) State health government
(e) Local health service
(f) Other government department
(g) Local government
(h) NACCHO / State affiliate / Aboriginal Community Controlled Organisation
(i) Medical College
(j) Specialty Society
(k) Nursing College
(l) Other health professional organisation

(m) Consumer organisation

(n) Other. Please specify:

____

____

____

(4) Which of the following is the most relevant description of the secondary or other guideline development groups(s)? [Circle the best one / or as many as apply?]

(a) Multidisciplinary non-government organisation (eg NHF, Cancer Council)

(b) NHMRC

(c) Other Federal Government body

(d) State government

(e) Local health service

(f) Other government department

(g) Local government

(h) Aboriginal Community Controlled Organisation

(i) Medical College

(j) Specialty Society

(k) Nursing College

(l) Other health professional organisation

(m) Consumer organisation

(n) Other. Specify:

____

____

____

(5) What is the year of publication of guideline: [20____] or Not stated _____

(6) Has this guideline been revised since publication?

[Yes/no/not sure]– if so, in what year? [20_____]

(7) Please complete the following information.(This information is directly sourced from the NHMRC Clinical Practice Guidelines Portal and has been determined by the portal administrator(s).

(a) Condition:

(b) Developer:

(c) Funder:

(d) Health care setting:

(e) Life Stage

(f) Is the guideline NHMRC approved? [Yes/no]

(g) Year of publication [20____]

(8) Which national health priority area or risk factor is this guideline?

a) asthma

b) diabetes

c) cancer

d) heart

e) stroke

f) vascular disease

e) osteoarthritis

f) rheumatoid arthritis and osteoporosis

g) injury

h) mental health.

i) tobacco smoking

j) risky and high risk alcohol use

k) physical inactivity

l) poor diet and nutrition

m) excess weight

n) high blood pressure

o) high blood cholesterol.

PART B: Relevance

1) Is the primary audience:
    a) Australian and international?
    b) Australian? (national focus/relevance)
    c) State or juridiction-based?

Briefly describe/state the population(s) for which the guideline would apply (eg entire Australian, population, "those at risk of heart disease", Indigenous Australians, people with a specific condition). Note below also the page numbers in the guidelines of any reference you write down

____

____

____

2) Estimate what percentage of the interventions in this guideline fall into the following categories:

(a) Therapeutic interventions: [__%]

(b) Behavioural interventions for a population group:

(whether preventive or clinical)[___%]

(c) Socio-environmental (structural) interventions: [___%]

(d) Political interventions: [_____%]

(e) Other:

____

____

____

3) What consumer/client representation is described in the guideline?

____

____

____

PART C: Quantifiable information

(1) Has specific reference in this guideline been made to the guideline being developed with reference to any particular framework or guide? eg AGREE instrument, NHMRC guidelines for guidelines, NICE guidelines - (as described in the guidelines development methods) [Yes/No].

(2) If yes, please list:- (note page numbers)

____

____

(3) Overall, to what extent has health equity, inequality or socioeconomic determinants impacting on health appeared to be a consideration in this guideline? [Choose which best applies]

(a) Not a consideration at all

(b) Considered a little

(c) Considered to a moderate extent

(d) Considered a lot

Provide page numbers in the guidelines to support this rating.

(4) a) Are there specific reference(s) in the guideline to the need to address inequity?

Yes/no/not sure. Specify details of this reference(s).

(5) In which sections of the guideline are there references to inequity/inequality in:

(a) Background information? [Yes/No]

(b) Recommendation/interventions? [Yes/No]

(c) Recommendations for further research? [Yes/No]

(d) Other? [Yes/No]

(e) Comments, including wording in each section

(6) Has primary evidence on social gradient informed the guidance recommendations?

[Yes/No].

Comment: If possible, comment on whether the social gradient relates to being a predictor of the incidence of ill-health, or related to patterns of care or treatment responsiveness or other factor.

(7) Have gaps in relation to data or research on social gradient and equity been identified in the guideline's literature review, the guideline itself or elsewhere in the document?

[Yes/No]. Comment:

(8) What has been documented in the guidelines as policy drivers for inclusion of equity in these guidelines (if at all): [circle appropriate choice(s)]

(a) Consistent with government or other policy [Yes/No]

(b) Equity is a priority for the guideline development organisation [Yes/No]

(c) Human rights justification [Yes/No]

(d) Evidence of impact of social gradient on the health issue/social intervention [Yes/No]

(e) Civic responsibility [Yes/No]

(f) Community requirement/feedback [Yes/No]

(g) Other stakeholder requirement [Yes/No]

(h) NHMRC guidelines on socioeconomic determinants [Yes/No]

(i) Other

(9) To what extent are socioeconomic determinants of health taken into account into guidelines?

Have the guideline developers made reference to health inequalities in the guidelines topic? [Yes/No]

Yes, if so, what, (detail reference)

If inequalities are referred to – inequality of what?

A) health care access health care provision, health care policy, outcome)?

Does the guideline identify any inequalities that are particularly unjust in relation to the health issue in question eg racial or gender inequalities. If so, what? Detail reference.

Does the guideline discuss or take into account social, environmental, economic factors/agents as disease factors or promoters of treatment?

PART E: APPRAISAL OF CRITERIA TAKEN FROM PREVIOUSLY DEVELOPED PAPERS (Dans et al, Tugwell et al.)

Application of the equity lens for guidelines as developed by *Dans et al*, - with equity gradients defined by PROGRESS (mnemonic): place of residence, race, occupation, gender, religion, education, socioeconomic status, social network and capital.

(1) Do the recommendations in the guidelines address a priority problem for disadvantaged populations? [Yes/No]. Comments:

(2) Is there a reason for the guideline developers to anticipate different effects of intervention in disadvantaged and privileged populations? [Yes/No]. Comments:

(3) Are the effects of the intervention valued differently by disadvantaged compared to privileged populations? [Yes/No]. Comments:

(4) Is specific attention given to minimising barriers to implementation in disadvantaged populations? [Yes/No]. Comments:

(5) Do plans for assessing the impact of the recommendations, include assessing impact /outcome in disadvantaged populations? [Yes/No]. Comments:

Part E: NHMRC guidelines on using socioeconomic evidence in clinical practice guidelines

(1) Are the NHMRC guidelines on using socioeconomic evidence in clinical practice guidelines referenced? [Yes/No]

(2) Has the methods section mentioned that the literature has been searched for socioeconomic inequalities in the condition of interest or intervention? [Yes/No].
Comments/describe, including, add page number:

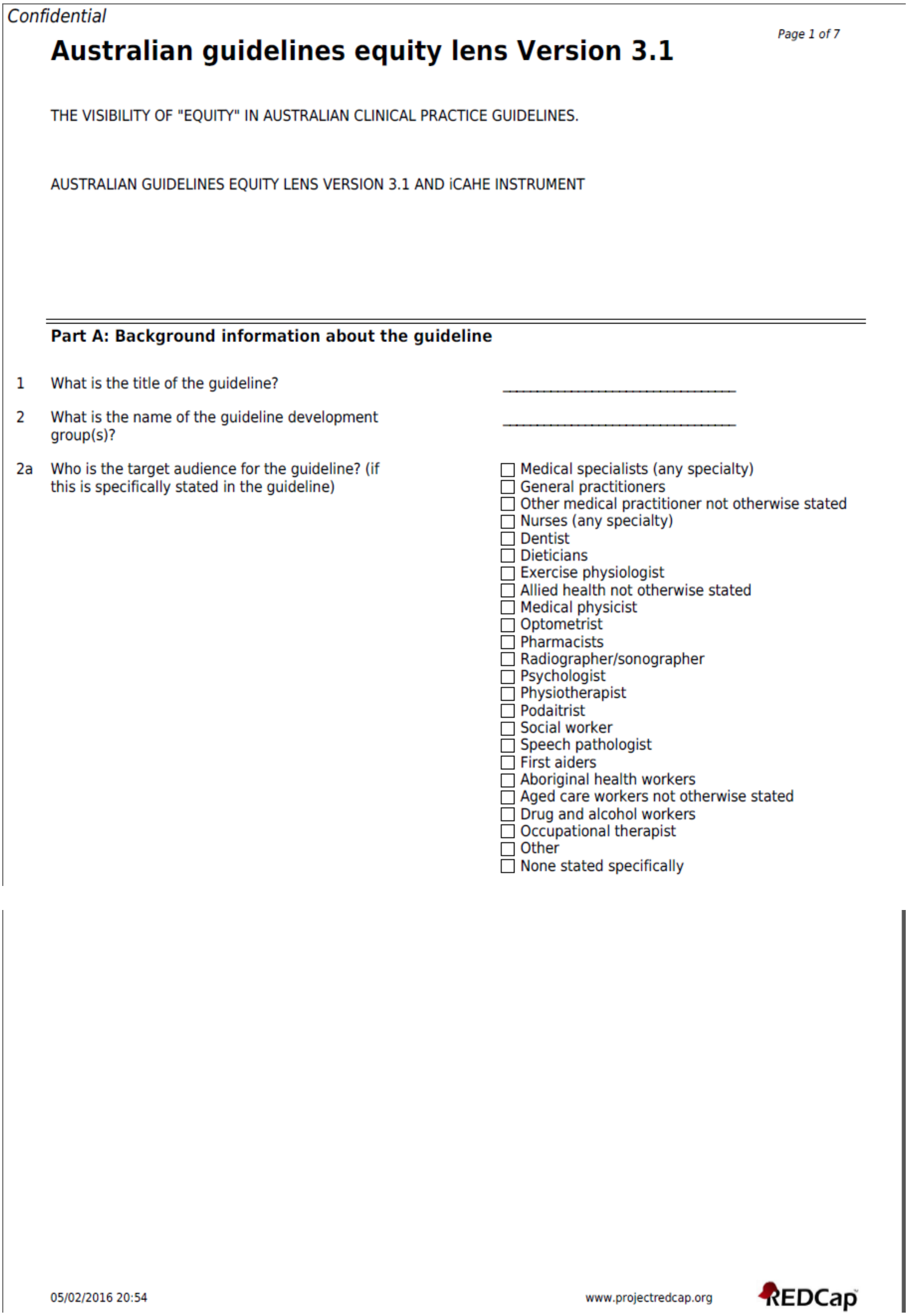
(3) Does the guideline present an analysis of the clinical issue related to socioeconomic position? [Yes/No]. Comments/details:

(5) Does the guideline report how the literature was searched to identify interventions that address barriers or opportunities for achieving equal health gains? [Yes/No].If so, specify how:

PART F: ANY OTHER RELEVANT INFORMATION/COMMENTS:

Appendix 4

Online Australian Guideline Equity Lens Version 3 questionnaire used for appraisal of 74 guidelines



Confidential

Page 1 of 7

Australian guidelines equity lens Version 3.1

THE VISIBILITY OF "EQUITY" IN AUSTRALIAN CLINICAL PRACTICE GUIDELINES.

AUSTRALIAN GUIDELINES EQUITY LENS VERSION 3.1 AND iCAHE INSTRUMENT

Part A: Background information about the guideline

1 What is the title of the guideline? ________________________________

2 What is the name of the guideline development group(s)? ________________________________

2a Who is the target audience for the guideline? (if this is specifically stated in the guideline)

- ☐ Medical specialists (any specialty)
- ☐ General practitioners
- ☐ Other medical practitioner not otherwise stated
- ☐ Nurses (any specialty)
- ☐ Dentist
- ☐ Dieticians
- ☐ Exercise physiologist
- ☐ Allied health not otherwise stated
- ☐ Medical physicist
- ☐ Optometrist
- ☐ Pharmacists
- ☐ Radiographer/sonographer
- ☐ Psychologist
- ☐ Physiotherapist
- ☐ Podaitrist
- ☐ Social worker
- ☐ Speech pathologist
- ☐ First aiders
- ☐ Aboriginal health workers
- ☐ Aged care workers not otherwise stated
- ☐ Drug and alcohol workers
- ☐ Occupational therapist
- ☐ Other
- ☐ None stated specifically

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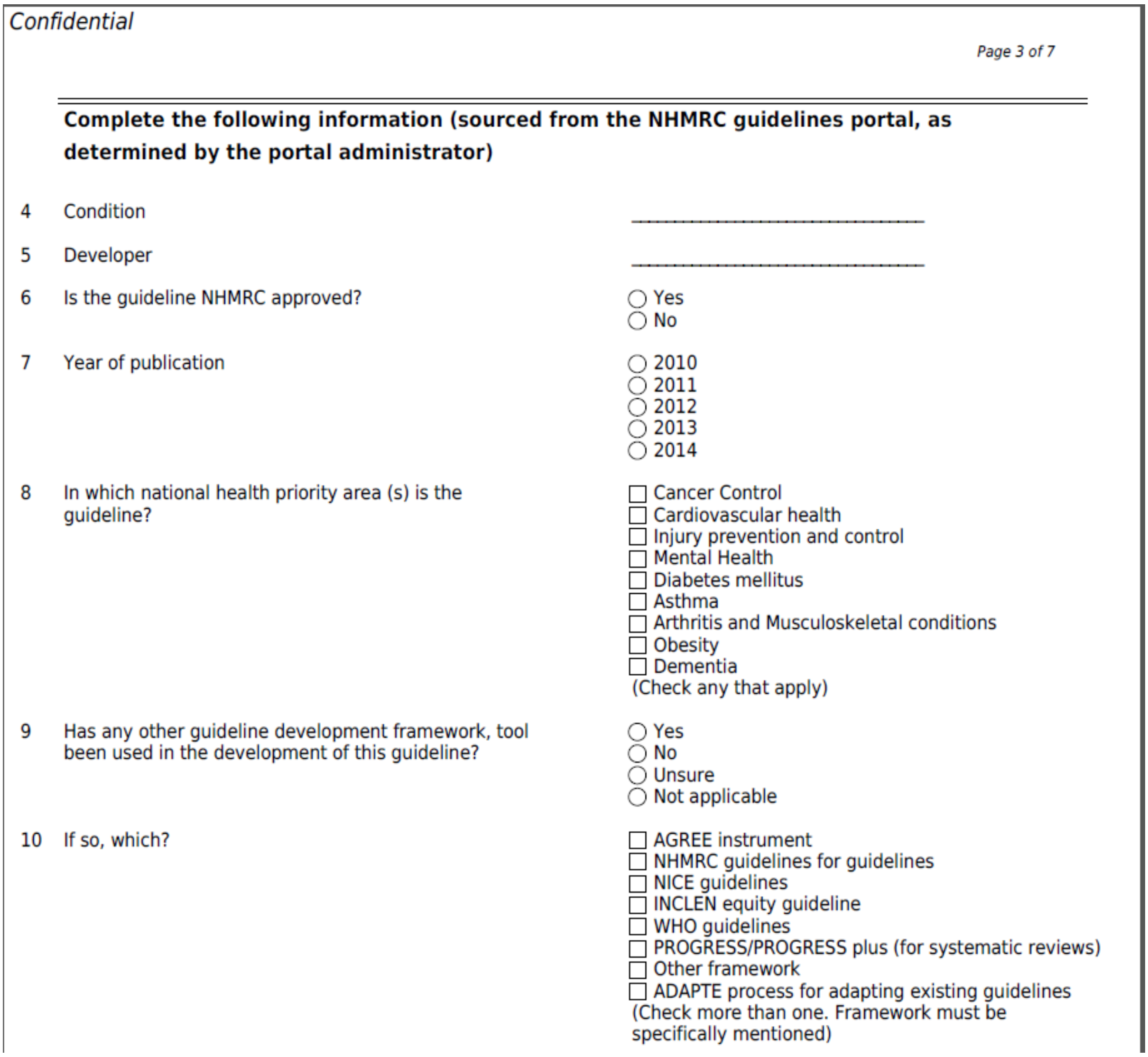
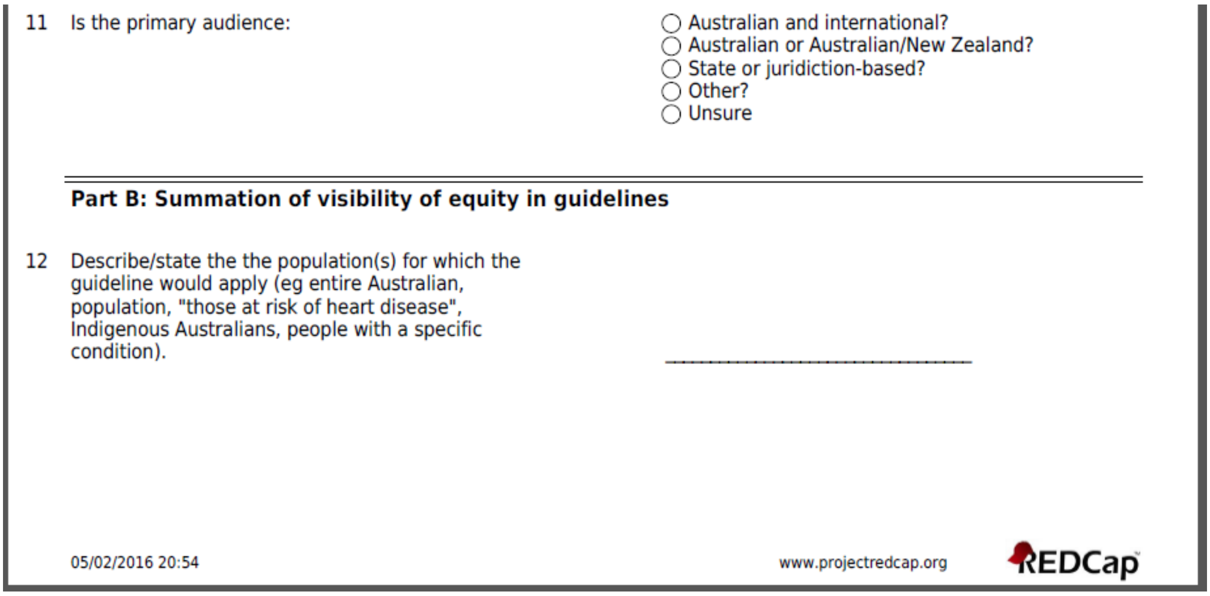
2b	Who is the target audience for the guideline? (presumed/assumed, if not specifically stated)	☐ Medical specialists (any specialty) ☐ General practitioners ☐ Other medical practitioner not otherwise stated ☐ Nurses (any specialty) ☐ Dentist ☐ Dieticians ☐ Exercise physiologist ☐ Allied health not otherwise stated ☐ Medical physicist ☐ Optometrist ☐ Pharmacists ☐ Radiographer/sonographer ☐ Psychologist ☐ Physiotherapist ☐ Podaitrist ☐ Social worker ☐ Speech pathologist ☐ First aiders ☐ Aboriginal health workers ☐ Aged care workers not otherwise stated ☐ Drug and alcohol workers ☐ Occupational therapist ☐ Other
3	Which of the following is the most relevant description of the primary guideline development group(s)?	☐ Multidisciplinary non-government organisation (eg Cancer Council, NHF) ☐ NHMRC ☐ Other Federal Government body ☐ State health government ☐ Local health service ☐ Other government department ☐ Local government ☐ Condition specific group ☐ NACCHO / State affiliate / Aboriginal Community Controlled Organisation ☐ Medical College ☐ Specialty Society ☐ Nursing College ☐ Other health professional organisation ☐ Consumer organisation ☐ Other. (Please check at least one box)
3a	Which of the following is the most relevant description of any other guideline development group(s)?	☐ Multidisciplinary non-government organisation (eg Cancer Council, NHF) ☐ NHMRC ☐ Other Federal Government body ☐ State health government ☐ Local health service ☐ Other government department ☐ Local government ☐ Condition specific group ☐ NACCHO / State affiliate / Aboriginal Community Controlled Organisation ☐ Medical College ☐ Specialty Society ☐ Nursing College ☐ Other health professional organisation ☐ Consumer organisation ☐ Other. (Please check at least one box)



Complete the following information (sourced from the NHMRC guidelines portal, as determined by the portal administrator)

4	Condition	________________________
5	Developer	________________________
6	Is the guideline NHMRC approved?	○ Yes ○ No
7	Year of publication	○ 2010 ○ 2011 ○ 2012 ○ 2013 ○ 2014
8	In which national health priority area (s) is the guideline?	☐ Cancer Control ☐ Cardiovascular health ☐ Injury prevention and control ☐ Mental Health ☐ Diabetes mellitus ☐ Asthma ☐ Arthritis and Musculoskeletal conditions ☐ Obesity ☐ Dementia (Check any that apply)
9	Has any other guideline development framework, tool been used in the development of this guideline?	○ Yes ○ No ○ Unsure ○ Not applicable
10	If so, which?	☐ AGREE instrument ☐ NHMRC guidelines for guidelines ☐ NICE guidelines ☐ INCLEN equity guideline ☐ WHO guidelines ☐ PROGRESS/PROGRESS plus (for systematic reviews) ☐ Other framework ☐ ADAPTE process for adapting existing guidelines (Check more than one. Framework must be specifically mentioned)



11	Is the primary audience:	○ Australian and international? ○ Australian or Australian/New Zealand? ○ State or juridiction-based? ○ Other? ○ Unsure

Part B: Summation of visibility of equity in guidelines

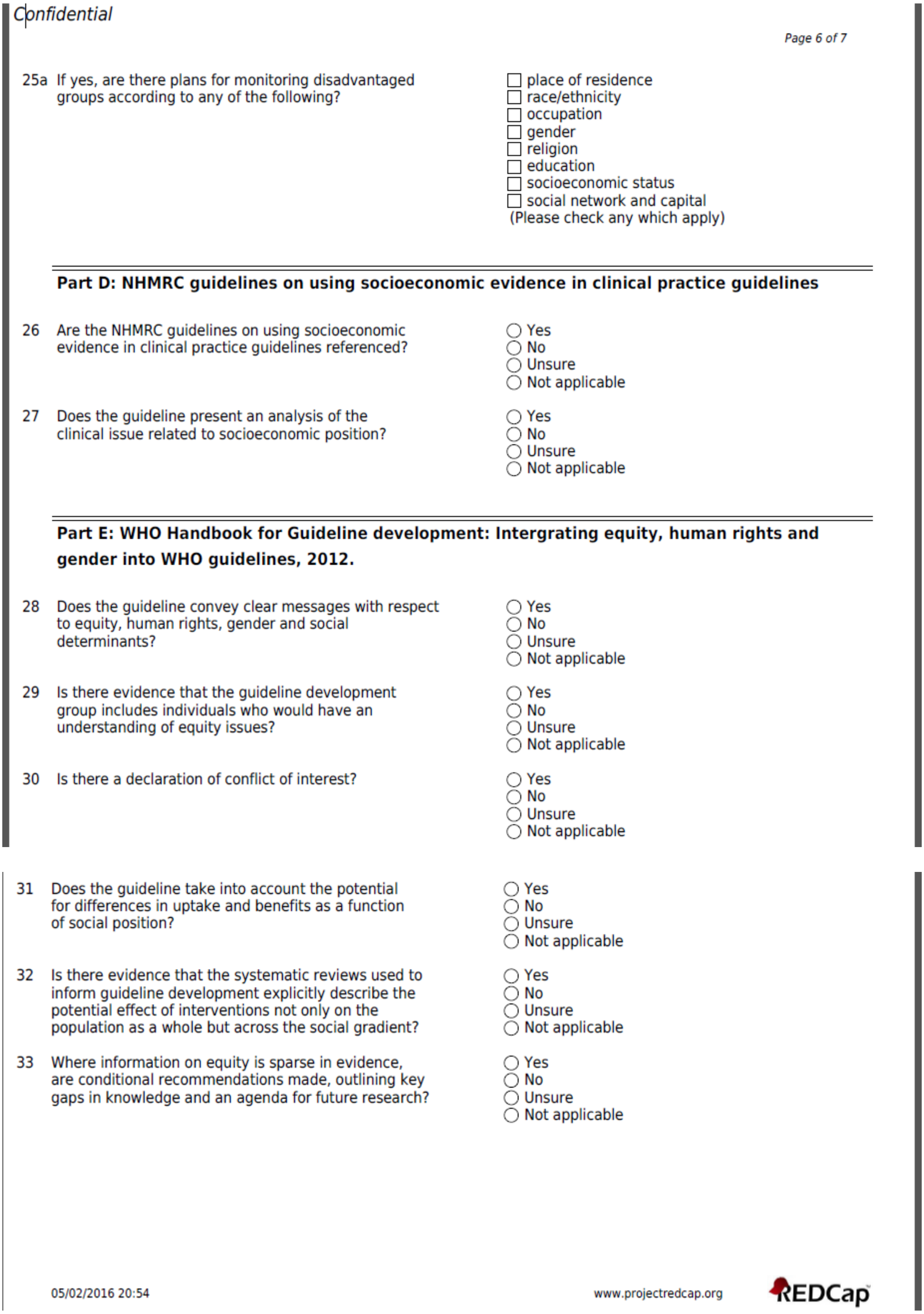
12	Describe/state the the population(s) for which the guideline would apply (eg entire Australian, population, "those at risk of heart disease", Indigenous Australians, people with a specific condition).	________________________

13	Please check the relevant box(es) if any of the following groups are given specific attention?	☐ Indigenous people/communities ☐ Children and young people ☐ Women ☐ Older people ☐ People with disabilities ☐ People from low socio-economic groups ☐ People from culturally and linguistically diverse backgrounds ☐ Persons with mental health issues (Tick as many as apply)
14	Is consumer/client representation described in the guideline development process?	○ Yes ○ No ○ Unsure ○ Not applicable
15	Are there specific reference(s) in the guideline about equity, inequality, human rights, socio-economic disadvantage or fairness?	○ Yes ○ No ○ Unsure ○ Not applicable
15a	If yes, specify details of this reference. If there is a specific references to words such as equity or inequity, specify here:	__________________________________
15b	In which sections of the guideline are there references to inequity/inequality/fairness/socio-economic disadvantage/socio-economic position?	☐ Background information or in literature review ☐ Recommendation/interventions/guidance ☐ Identification of gaps or recommendations for further research ☐ Other (Check as many as appropriate if relevant/applicable)
16	Has evidence on social gradient or socio-economic position informed the guidance recommendations?	○ Yes ○ No ○ Unsure ○ Not applicable
17	Is there mention of the PROGRESS lens for systematic reviews being taken into account into evidence synthesis?	○ Yes ○ No ○ Unsure ○ Not applicable
18	Have gaps in relation to data or research on social gradient and equity been identified in the guidelines?	○ Yes ○ No ○ Unsure ○ Not applicable
18a	If yes, where?	☐ Guideline literature review ☐ Guidance section/recommendations ☐ Summary/conclusions ☐ Specific section relating to gaps/further research ☐ Other (Check as many as appropriate)

19	If there is evidence of equity being considered or addressed in the guideline, what has been documented in the guidelines as the reason(s), rationale for including equity in these guidelines (if at all)?	☐ Consistent with government or other policy ☐ Equity is stated a priority for the guideline development organisation ☐ Human rights or fairness justification] ☐ Evidence of impact of social gradient on the health issue/social intervention ☐ Civic responsibility ☐ Community requirement/feedback ☐ Other stakeholder requirement ☐ NHMRC guidelines on socioeconomic determinants ☐ WHO Handbook for Guideline development - equity chapter ☐ Other (Check all that apply)

Part C: Appraisal of criteria using the INCLEN equity lens (Dans et al.)

20	Do the recommendations in the guidelines address a priority problem for disadvantaged populations?	○ Yes ○ No ○ Unsure ○ Not applicable
20a	If so, which population(s)?	__________________________________
20b	If yes, is there discussion of the burden of disease in disadvantaged populations?	○ Yes ○ No ○ Unsure ○ Not applicable
21	Is there a reason for the guideline developers to anticipate different effects of intervention in disadvantaged and privileged populations?	○ Yes ○ No ○ Unsure ○ Not applicable
21a	If yes, if there a discussion of the differences between disadvantaged and privileged populations in terms of any of the following?	☐ biology of the disease ☐ adherence ☐ risk factors for the condition (Check as many as are appropriate)
22	Are the effects of the intervention VALUED DIFFERENTLY by disadvantaged compared to privileged populations?	☐ Yes ☐ No ☐ Unsure ☐ Not applicable
23	Is there evidence of assessment of VALUES through any of the following (about what the group might value)?	☐ consultations with disadvantaged groups ☐ involvement of caregivers ☐ reference to relevant research ☐ no evidence that values are assessed (Check as many as appropriate)
24	Is specific attention given to minimising barriers to implementation in disadvantaged populations or strategies to overcoming these barriers?	☐ Yes ☐ No ☐ Unsure ☐ Not applicable
24a	If yes, please specify:	__________________________________
25	Do plans for assessing the impact of the recommendations include assessing impact /outcome in disadvantaged populations?	○ Yes ○ No ○ Unsure ○ Not applicable



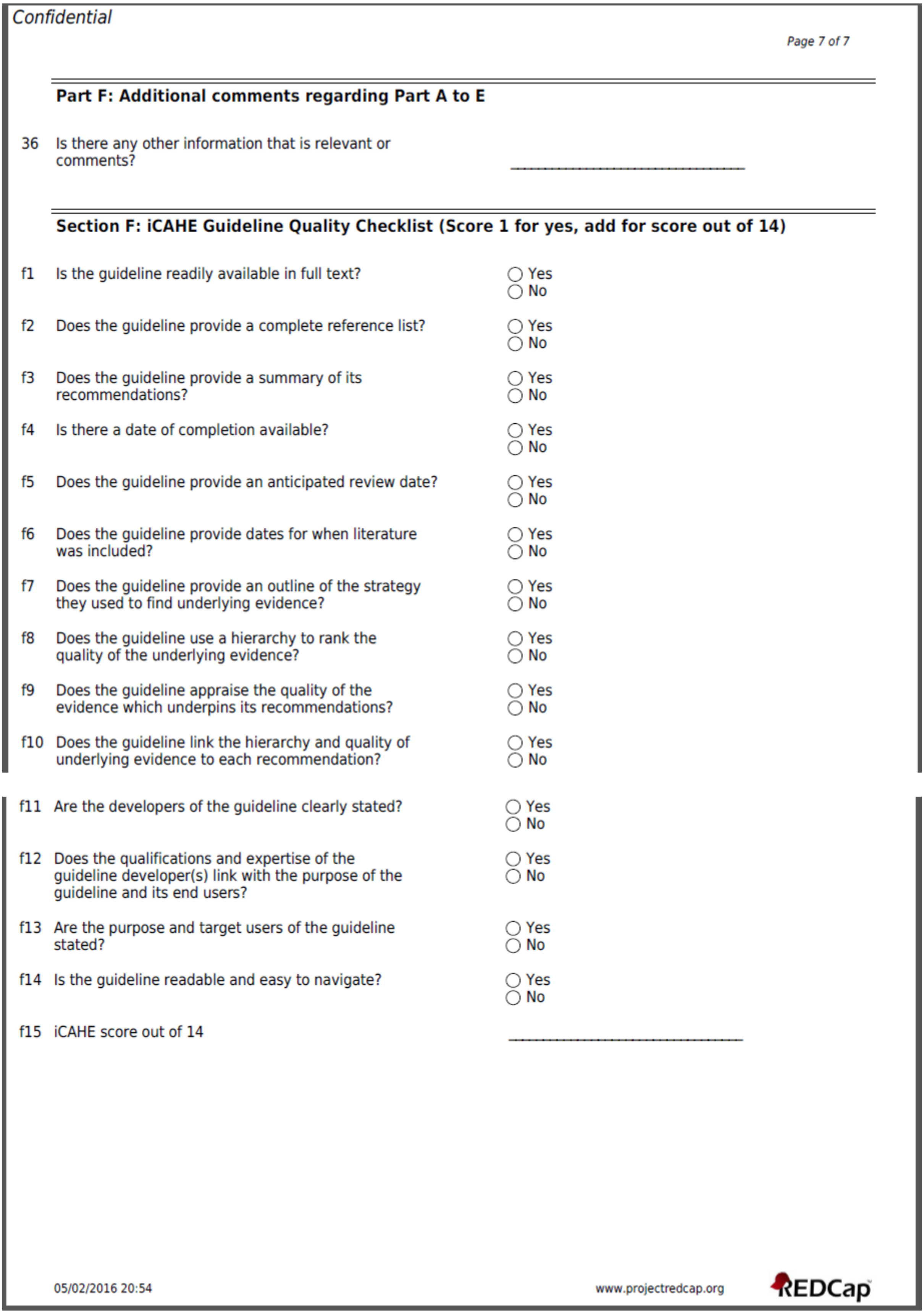
25a	If yes, are there plans for monitoring disadvantaged groups according to any of the following?	☐ place of residence ☐ race/ethnicity ☐ occupation ☐ gender ☐ religion ☐ education ☐ socioeconomic status ☐ social network and capital (Please check any which apply)

Part D: NHMRC guidelines on using socioeconomic evidence in clinical practice guidelines

26	Are the NHMRC guidelines on using socioeconomic evidence in clinical practice guidelines referenced?	○ Yes ○ No ○ Unsure ○ Not applicable
27	Does the guideline present an analysis of the clinical issue related to socioeconomic position?	○ Yes ○ No ○ Unsure ○ Not applicable

Part E: WHO Handbook for Guideline development: Intergrating equity, human rights and gender into WHO guidelines, 2012.

28	Does the guideline convey clear messages with respect to equity, human rights, gender and social determinants?	○ Yes ○ No ○ Unsure ○ Not applicable
29	Is there evidence that the guideline development group includes individuals who would have an understanding of equity issues?	○ Yes ○ No ○ Unsure ○ Not applicable
30	Is there a declaration of conflict of interest?	○ Yes ○ No ○ Unsure ○ Not applicable
31	Does the guideline take into account the potential for differences in uptake and benefits as a function of social position?	○ Yes ○ No ○ Unsure ○ Not applicable
32	Is there evidence that the systematic reviews used to inform guideline development explicitly describe the potential effect of interventions not only on the population as a whole but across the social gradient?	○ Yes ○ No ○ Unsure ○ Not applicable
33	Where information on equity is sparse in evidence, are conditional recommendations made, outlining key gaps in knowledge and an agenda for future research?	○ Yes ○ No ○ Unsure ○ Not applicable



Part F: Additional comments regarding Part A to E

36	Is there any other information that is relevant or comments?	____

Section F: iCAHE Guideline Quality Checklist (Score 1 for yes, add for score out of 14)

f1	Is the guideline readily available in full text?	○ Yes ○ No
f2	Does the guideline provide a complete reference list?	○ Yes ○ No
f3	Does the guideline provide a summary of its recommendations?	○ Yes ○ No
f4	Is there a date of completion available?	○ Yes ○ No
f5	Does the guideline provide an anticipated review date?	○ Yes ○ No
f6	Does the guideline provide dates for when literature was included?	○ Yes ○ No
f7	Does the guideline provide an outline of the strategy they used to find underlying evidence?	○ Yes ○ No
f8	Does the guideline use a hierarchy to rank the quality of the underlying evidence?	○ Yes ○ No
f9	Does the guideline appraise the quality of the evidence which underpins its recommendations?	○ Yes ○ No
f10	Does the guideline link the hierarchy and quality of underlying evidence to each recommendation?	○ Yes ○ No
f11	Are the developers of the guideline clearly stated?	○ Yes ○ No
f12	Does the qualifications and expertise of the guideline developer(s) link with the purpose of the guideline and its end users?	○ Yes ○ No
f13	Are the purpose and target users of the guideline stated?	○ Yes ○ No
f14	Is the guideline readable and easy to navigate?	○ Yes ○ No
f15	iCAHE score out of 14	____

Appendix 5

Modified Australian Guideline Equity Lens Version 3 used for inter-rater reliability testing

Australian Guideline Equity Lens- inter-rater reliability assessment

THE VISIBILITY OF "EQUITY" IN AUSTRALIAN CLINICAL PRACTICE GUIDELINES.

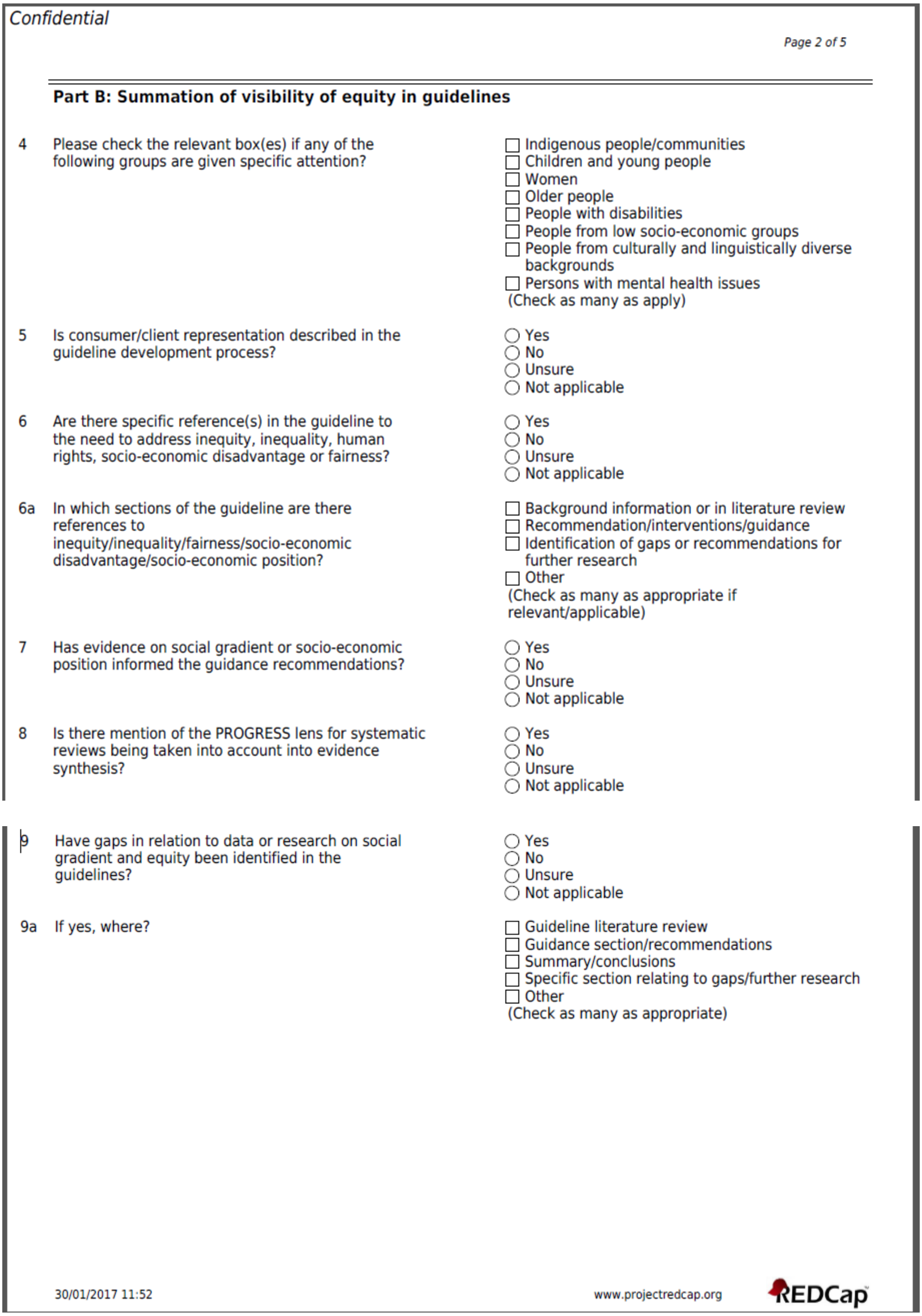
AUSTRALIAN GUIDELINES EQUITY LENS VERSION 3.1 AND iCAHE INSTRUMENT

Could you please complete this audit using the guideline provided.

Please note that some of the questions may seem repetitive. This is deliberate as I am looking at the internal validity of the instrument as well as the predictive value of some questions.

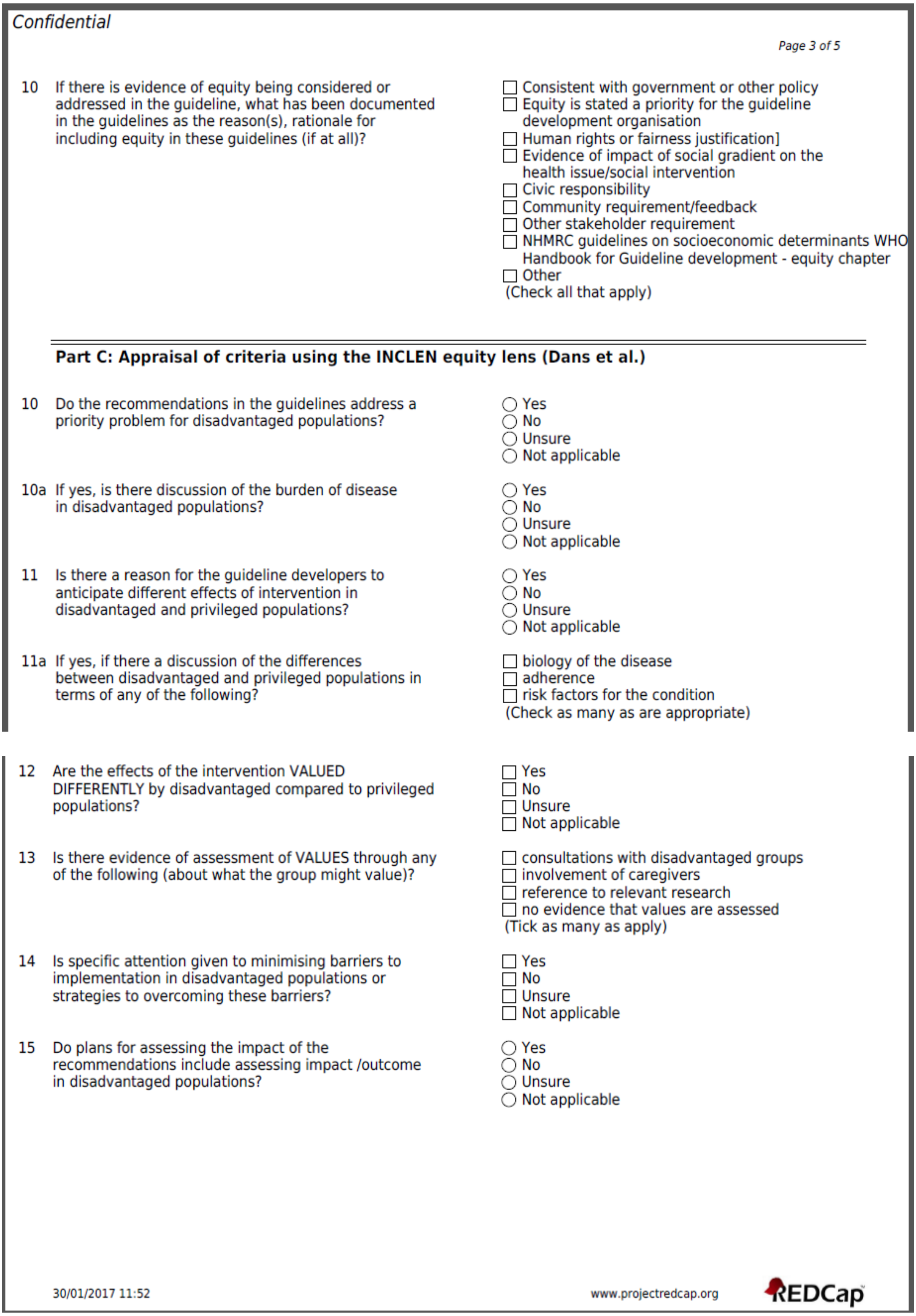
Part A Preliminary questions

1	What is the title of the guideline?	________________________________
2	Has any other guideline development framework, tool been used in the development of this guideline?	○ Yes ○ No ○ Unsure ○ Not applicable
2a	If so, which?	☐ AGREE instrument ☐ NHMRC guidelines for guidelines ☐ NICE guidelines ☐ INCLEN equity guideline ☐ WHO guidelines ☐ PROGRESS/PROGRESS plus (for systematic reviews) ☐ Other (Tick more than one. Framework must be specifically mentioned)
3	Is the primary audience:	○ Australian and international? ○ Australian? ○ State or juridiction-based? ○ Other? ○ Unsure



Part B: Summation of visibility of equity in guidelines

4	Please check the relevant box(es) if any of the following groups are given specific attention?	☐ Indigenous people/communities ☐ Children and young people ☐ Women ☐ Older people ☐ People with disabilities ☐ People from low socio-economic groups ☐ People from culturally and linguistically diverse backgrounds ☐ Persons with mental health issues (Check as many as apply)
5	Is consumer/client representation described in the guideline development process?	○ Yes ○ No ○ Unsure ○ Not applicable
6	Are there specific reference(s) in the guideline to the need to address inequity, inequality, human rights, socio-economic disadvantage or fairness?	○ Yes ○ No ○ Unsure ○ Not applicable
6a	In which sections of the guideline are there references to inequity/inequality/fairness/socio-economic disadvantage/socio-economic position?	☐ Background information or in literature review ☐ Recommendation/interventions/guidance ☐ Identification of gaps or recommendations for further research ☐ Other (Check as many as appropriate if relevant/applicable)
7	Has evidence on social gradient or socio-economic position informed the guidance recommendations?	○ Yes ○ No ○ Unsure ○ Not applicable
8	Is there mention of the PROGRESS lens for systematic reviews being taken into account into evidence synthesis?	○ Yes ○ No ○ Unsure ○ Not applicable
9	Have gaps in relation to data or research on social gradient and equity been identified in the guidelines?	○ Yes ○ No ○ Unsure ○ Not applicable
9a	If yes, where?	☐ Guideline literature review ☐ Guidance section/recommendations ☐ Summary/conclusions ☐ Specific section relating to gaps/further research ☐ Other (Check as many as appropriate)



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10	If there is evidence of equity being considered or addressed in the guideline, what has been documented in the guidelines as the reason(s), rationale for including equity in these guidelines (if at all)?	☐ Consistent with government or other policy ☐ Equity is stated a priority for the guideline development organisation ☐ Human rights or fairness justification] ☐ Evidence of impact of social gradient on the health issue/social intervention ☐ Civic responsibility ☐ Community requirement/feedback ☐ Other stakeholder requirement ☐ NHMRC guidelines on socioeconomic determinants WHO Handbook for Guideline development - equity chapter ☐ Other (Check all that apply)

Part C: Appraisal of criteria using the INCLEN equity lens (Dans et al.)

10	Do the recommendations in the guidelines address a priority problem for disadvantaged populations?	○ Yes ○ No ○ Unsure ○ Not applicable
10a	If yes, is there discussion of the burden of disease in disadvantaged populations?	○ Yes ○ No ○ Unsure ○ Not applicable
11	Is there a reason for the guideline developers to anticipate different effects of intervention in disadvantaged and privileged populations?	○ Yes ○ No ○ Unsure ○ Not applicable
11a	If yes, if there a discussion of the differences between disadvantaged and privileged populations in terms of any of the following?	☐ biology of the disease ☐ adherence ☐ risk factors for the condition (Check as many as are appropriate)
12	Are the effects of the intervention VALUED DIFFERENTLY by disadvantaged compared to privileged populations?	☐ Yes ☐ No ☐ Unsure ☐ Not applicable
13	Is there evidence of assessment of VALUES through any of the following (about what the group might value)?	☐ consultations with disadvantaged groups ☐ involvement of caregivers ☐ reference to relevant research ☐ no evidence that values are assessed (Tick as many as apply)
14	Is specific attention given to minimising barriers to implementation in disadvantaged populations or strategies to overcoming these barriers?	☐ Yes ☐ No ☐ Unsure ☐ Not applicable
15	Do plans for assessing the impact of the recommendations include assessing impact /outcome in disadvantaged populations?	○ Yes ○ No ○ Unsure ○ Not applicable

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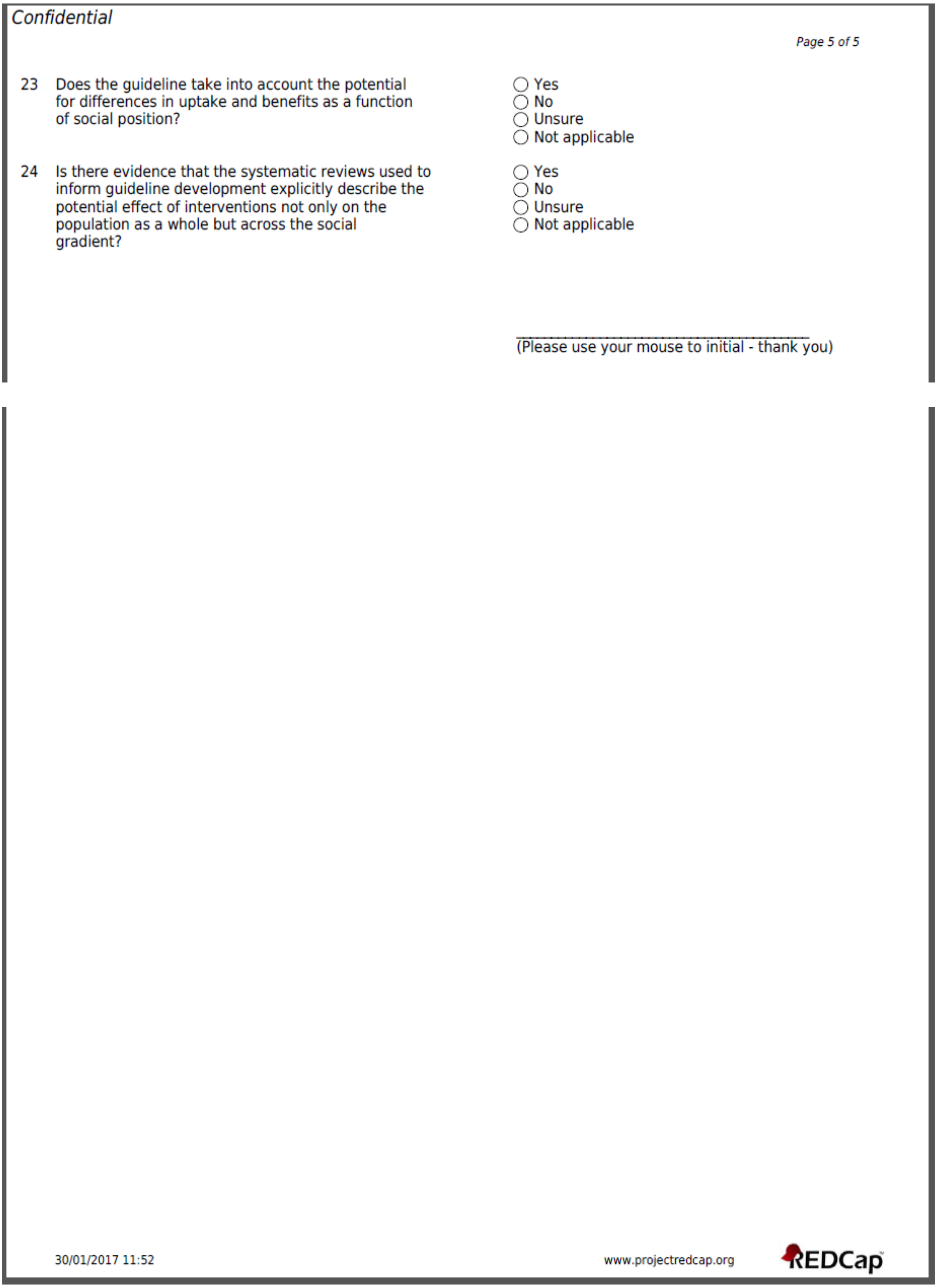
15a	If yes, are there plans for monitoring disadvantaged groups according to any of the following?	☐ place of residence ☐ race/ethnicity ☐ occupation ☐ gender ☐ religion ☐ education ☐ socioeconomic status ☐ social network and capital (Please check any which apply)

Part D: NHMRC guidelines on using socioeconomic evidence in clinical practice guidelines

16	Are the NHMRC guidelines on using socioeconomic evidence in clinical practice guidelines referenced?	○ Yes ○ No ○ Unsure ○ Not applicable
17	Does the guideline present an analysis of the clinical issue related to socioeconomic position?	○ Yes ○ No ○ Unsure ○ Not applicable
18	Does the guideline present an analysis of the clinical issue related to socioeconomic position?	○ Yes ○ No ○ Unsure ○ Not applicable

Part E: WHO Handbook for Guideline development: Intergrating equity, human rights and gender into WHO guidelines, 2012.

19	Does the guideline convey clear messages with respect to equity, human rights, gender and social determinants?	○ Yes ○ No ○ Unsure ○ Not applicable
20	Please check the relevant box(es) if any of the following stratifiers are identified in the guideline recommendations	☐ place of residence ☐ race/ethnicity ☐ occupation ☐ gender ☐ religion ☐ education ☐ socioeconomic status ☐ social network and capital ☐ Age ☐ Disability (Please check any which apply)
21	Is there evidence that the guideline development group includes individuals who would have an understanding of equity issues?	○ Yes ○ No ○ Unsure ○ Not applicable
22	Is there a declaration of conflict of interest?	○ Yes ○ No ○ Unsure ○ Not applicable



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23	Does the guideline take into account the potential for differences in uptake and benefits as a function of social position?	○ Yes ○ No ○ Unsure ○ Not applicable
24	Is there evidence that the systematic reviews used to inform guideline development explicitly describe the potential effect of interventions not only on the population as a whole but across the social gradient?	○ Yes ○ No ○ Unsure ○ Not applicable

____
(Please use your mouse to initial - thank you)

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Appendix 6

Summary briefing for SToRE Committee

Summary briefing for the Synthesis and Translation of Research Evidence Advisory Committee of the National Health and Medical Research Council regarding research about the visibility of equity and socioeconomic determinants in Australian clinical practice guidelines

Prepared by Leena Gupta, Flinders University, July 2017

Context: The Synthesis and Translation of Research Evidence Advisory Committee of the National Health and Medical Research Council will be advising on the update of the NHMRC *Handbook on Standards for Clinical Practice Guidelines* over the next 2 years. This briefing describes research conducted relating to one aspect of clinical practice guideline development that has implications for public health policy in the area of clinical practice guideline development and approval. Specifically, the research addresses the visibility of equity and socioeconomic determinants in Australian clinical practice guidelines on the NHMRC Australian Clinical Practice Guidelines Portal. The research objectives, methods and findings are summarised below. Recommendations for consideration by the NHMRC Synthesis and Translation of Research Evidence Advisory Committee are also included.

Research summary

The visibility of equity and socioeconomic determinants in Australian clinical practice guidelines: Leena Gupta, Jeanette Ward, Paul Ward.

Clinical practice guidelines (CPGs) are systematic statements that communicate evidence-based recommendations about health care. CPGs have potential to create inequity systemically when providing treatment and care, for example, if disadvantaged groups are not considered specifically in recommendations, they may have poorer health care access or health outcomes. CPGs may also lessen inequity by including recommendations which redress the impact of disadvantage in healthcare delivery, for example, those which specifically address outcomes in disadvantaged groups. The focus of the research was twofold; firstly to examine, using an equity lens developed by the author, whether consideration of equity, socioeconomic determinants and disadvantaged groups, including Aboriginal and Torres Strait populations, is visible in Australian clinical practice guidelines on the National Health and Medical Research Council's (NHMRC) Australian Clinical Practice Guidelines Portal, and secondly to identify the characteristics of guidelines that demonstrate consideration of equity.

To develop the equity lens, a systematic literature search and critical appraisal of the literature was conducted to identify any existing instruments and to clarify how equity and socioeconomic considerations are currently described in guidelines. Then, the Australian Guideline Equity Lens (AGEL) was developed using a policy Delphi process, followed by pilot testing. As described in this dissertation, the Delphi process involved rounds of consultation with experts in the topics of equity, CPGs and clinical medicine. Face validity, usability and inter-rater reliability of the lens were assessed. Psychometric qualities of the lens were sound.

Seventy-four clinical practice guidelines in Australian National Health Priority areas accessed via the NHMRC's Clinical Practice Guideline Portal, published between 2010 and 2014, were reviewed using an online version of the AGEL. Data were collected on whether and how equity, socioeconomic determinants and disadvantaged populations were considered, and the development processes and other characteristics of the guidelines were assessed. The association between methodological quality of each guideline and inclusion of equity considerations was examined quantitatively.

Overall, equity, socioeconomic determinants and the needs of specific populations were invisible in the majority of Australian CPGs studied. Only 31% of CPGs made reference to socioeconomic considerations and 12 guidelines identified gaps in research relating to equity or how socioeconomic determinants might impact in relation to the guideline topic. Specific consideration of the needs of Aboriginal and Torres Strait Islander patients was addressed in less than half (45%) of the national guidelines studied. There was no significant association between consideration of equity and socioeconomic determinants in CPGs and the methodological quality of the guidelines.

There was a significant association, however, between consumer involvement in guideline development and the consideration of socioeconomic determinants in guidelines. Analysis also demonstrated an association between consumer involvement in guidelines development and consideration of the needs of Aboriginal and Torres Strait Islander populations.

This research has identified that the majority of Australian CPGs in National Health Priority Areas accessible via the NHMRC Clinical Practice Guidelines Portal did not consider equity and socioeconomic determinants in the guidelines.

This study has implications for public health policy relating to the national standards and processes for CPG development in Australia. For example, parameters from the Australian Guidelines Equity Lens could be incorporated into national standards for CPGs to strengthen considerations of equity, socioeconomic determinants and disadvantaged populations in the future.

Recommendations for consideration by the NHMRC Synthesis and Translation of Research Evidence Advisory Committee (SToRE) in relation to the proposed revision of the Handbook for clinical practice guideline development (previously referred to as NHMRC *Standards for Clinical Practice Guidelines*)

That the SToRE Advisory Group:

1) *Notes that the evidence-based premise of this research is that consideration of equity, socioeconomic determinants and Aboriginal and Torres Strait Islander populations is important in clinical practice guidelines development because recommendations in guidelines have the potential to worsen inequity or to redress the impact of disadvantage in health care delivery. This research has demonstrated that equity, socioeconomic determinants and disadvantaged populations (including Aboriginal and Torres Strait Islander*

populations) are poorly considered in Australian clinical practice guidelines in National Health Priority Areas. This has implications for public health policy in Australia as it may mean that Australian guidelines might create further inequalities in health care delivery or in health outcomes for those who are socioeconomically disadvantaged. This is particularly the case because the National Health Priority Areas cover conditions that are highly prevalent in the Australian population and also because Aboriginal and Torres Strait Islander Health is a national priority and there are already significant gaps in health outcomes and health care outcomes.

2) *Considers the inclusion of a usable section on equity, socioeconomic determinants and disadvantaged populations in the next version of the standards for clinical practice guidelines that takes into account the parameters which were developed for the AGEL.*

3) *Notes that consumer involvement and use of the NHMRC standards was associated with consideration of equity, socioeconomic determinants, and consideration of Aboriginal and Torres Strait Islander populations. Hence, the need for consumer involvement in development and the use of the revised standards in all critical guideline development should be strongly encouraged.*

4) *Notes that the previous NHMRC document, "Using Socioeconomic Evidence in Clinical Practice Guidelines" was not referenced in any of the guidelines studied in this research, suggesting that this document is not sufficient for encouraging consideration of equity, socioeconomic determinants or disadvantaged groups in clinical practice guidelines.*

5) *Considers using the online AGEL, which has been extensively used in this research and has sound psychometric properties (or a modification of it), to appraise future guidelines that might be submitted for approval to the NHMRC, in addition to using the traditional instruments which might be used to appraise guideline quality such as the AGREE instrument.*
